KANSAS DEPARTMENT OF HEALTH & ENVIRONMENT
Division of Health & Environmental Laboratories

STANDARDS FOR ACCREDITATION OF ENVIRONMENTAL LABORATORIES
February 2004

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This standard sets the general requirements for laboratory accreditation. When more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. When it is not clear which requirements are more stringent, the standard from the method or regulation is to be followed. This standard is for use by environmental testing laboratories in the development and implementation of their quality systems and shall be used by the department, in assessing the competence of environmental laboratories.

Part I - Definitions.

(1) “Acceptance Criteria” means the specified limits placed on characteristics of an item, process, or service defined in requirement documents.

(2) “Accuracy” means the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator.

(3) “Batch” means environmental samples which are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A preparation batch is composed of one to 20 environmental samples of the same matrix, meeting the above mentioned criteria, and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An analytical batch is composed of 20 environmental samples of the same matrix analyzed together with the same process and personnel, using the same lot(s) of reagents, and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An analytical batch can also be composed of prepared environmental samples (extracts, digestates, or concentrates) which are analyzed together as a group and can include prepared samples originating from various environmental matrices, and can exceed 20 samples.

(4) “Blank” means an analyte free matrix used to monitor contamination during sampling, transportation, storage, or analysis.

(5) “Calibration” means the determination by measurement or comparison with a standard, the

correct value of each scale reading on a meter, instrument, or other device.

(6) “Certified Reference Material (CRM)” means a reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body.

(7) “Chain of custody” (Legal) means procedures employed to record the possession of samples from the time of sampling until analysis and are performed at the special request of the client. These protocols include the use of a Chain of Custody Form that documents the collection, transport, and receipt of compliance samples by the laboratory. In addition, these protocols document all handling of the samples within the laboratory.

(8) “Chain of Custody” (Form) means a record that documents the possession of the samples from the time of collection to receipt in the laboratory. This record generally includes: the number and types of containers; the mode of collection; collector; time of collection; preservation; and requested analyses

(9) “Confirmation” means the verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to:
Second column confirmation,
Alternate wavelength,
Derivatization,
Mass spectral interpretation,
Alternative detectors, or
Additional cleanup procedures.

(10) “Data Reduction” means the process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, etc., and collation into a more useable form.

(11) "Laboratory control sample" means a known matrix spiked with the compound(s) representative of the target analytes.

(12) “Matrix” means a component or substance which contains the parameter of interest. The following matrix types are used for batch determination:

(A) Aqueous. Includes surface water, groundwater and wastewater effluents.
(B) Drinking water. Aqueous samples which are designated as public or private drinking water supplies or potential public or private drinking water supplies.

(C) Saline/Estuaries. Any aqueous sample from an ocean or estuary, or other natural source.
(D) Non-aqueous liquid. Organic liquids with less than 15 percent settleable solids.
(E) Biological Tissue. Any sample of biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.
(F) Solids. Includes soils, sediments, sludges and other matrices with greater than 15 percent settleable solids.
(G) Chemical waste. A product or by-product of a process that results in a matrix not defined above.
(H) Air. Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter, or other device.

(13) "Matrix spike" means an aliquot of sample spiked with a known concentration of target analyte(s). The spiking occurs prior to sample preparation and analysis.

(14) "Matrix spike duplicates" means intra-laboratory split samples spiked with identical concentrations of target analyte(s). The spiking occurs prior to sample preparation and analysis.

(15) "Method blank" means an analyte-free matrix to which all reagents are added in the same volumes or proportions as used in sample processing. The method blank should be carried through the complete sample preparation and analytical procedure.

(16) "Method detection limit (MDL)" means the minimum concentration of a substance that can be measured and reported with a 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix type containing the analyte.

(17) “NIST” means the National Institute of Standards and Technology of the U.S. Department of Commerce. An agency of the US Department of Commerce’s Technology Administration.

(18) “National Environmental Laboratory Accreditation Conference” (NELAC) means a voluntary organization of State and Federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories. A subset of NELAP.

(19) “National Environmental Laboratory Accreditation Program” (NELAP): the overall National
Environmental Laboratory Accreditation Program of which NELAC is a part.

(20) “Precision” means the degree to which a set of observations or measurements of the same property obtained under similar conditions, conform to themselves; a data quality indicator. Precision is expressed as standard deviation, variance or range, in either absolute or relative terms.

(21) “Procedure” means the specified way to carry out an activity or a process. Procedures can be documented or not.

(22) “Protocol” means a detailed written procedure for field and/or laboratory operation (e.g., sampling, analysis) which must be strictly followed.

(23) “Quality Assurance” means an integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.

(24) “Quality Control” means the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users.

(25) “Quality Manual” means a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users.

(26) “Quality System” means a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC.

(27) “Quantitation Limits” means levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported at a specified degree of confidence.

(28) “Raw Data” means any original factual information from a measurement activity or study recorded in a laboratory notebook, worksheets, records, memoranda, notes, or exact copies thereof that are necessary for the reconstruction and evaluation of the report of the activity or study. Raw data may include photography, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments. If exact copies of raw data have been prepared (e.g., tapes which have been transcribed verbatim, data and verified accurate by signature), the exact copy or exact transcript may be submitted.

(29) “Reference Material” means a material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

(30) “Reference Method” means a method of known and documented accuracy and precision issued by an organization recognized as competent to do so.

(31) “Reference Standard” means a standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.

(32) “Reference Toxicant” means the toxicant used in performing toxicity tests to indicate the sensitivity of a test organism and to demonstrate the laboratory’s ability to perform the test correctly and obtain consistent results.

(33) “Selectivity” (Analytical chemistry) means the capability of a test method or instrument to respond to a target substance or constituent in the presence of non-target substances.

(34) “Standard Operating Procedures” (SOPs) means a written document which details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks.

(35) “Standardized Reference Material” (SRM) means a certified reference material produced by the U.S. National Institute of Standards and Technology or other equivalent organization and characterized for absolute content, independent of analytical method.

(36) “Statistical Minimum Significant Difference” (SMSD) means the minimum difference between the control and a test concentration that is statistically significant; a measure of test sensitivity or power. The power of a test depends in part on the number of replicates per concentration, the significance level selected, e.g., 0.05, and the type of statistical analysis. If the variability remains constant, the sensitivity of the test increases as the number of replicates is increased.

(37) “Traceability” means the property of a result of a measurement whereby it can be related to appropriate standard, generally international or national standard, through an unbroken chain of comparisons.

(38) “Test” means a technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical

phenomenon, process or service according to a specified procedure. The result of a test is normally recorded in a document sometimes called a test report or a test certificate.

(39) “Test Method” means an adoption of a scientific technique for a specific measurement problem, as documented in a laboratory SOP or published by a recognized authority.

(40) “Test Sensitivity/Power” means the minimum significant difference (MSD) between the control and test concentration that is statistically significant. It is dependent on the number of replicates per concentration, the selected significance level, and the type of statistical analysis.

(41) “Tolerance Chart” means a chart in which the plotted quality control data is assessed via a tolerance level (e.g. +/- 10% of a mean) based on the precision level judged acceptable to meet overall quality/data use requirements instead of a statistical acceptance criteria (e.g. +/- 3 sigma) (applies to radiochemistry laboratories).

(42) “Validation” means the confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

(43) “Verification” means confirmation by examination and provision of evidence that specified requirements have been met. In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment. The result of verification leads to a decision either to restore in service, to perform adjustment, to repair, to downgrade, or to declare obsolete.

(44) “Work Cell” means a well defined group of analysts that together perform the analysis.

Part II - Organization and Personnel requirements.

(1) Organization. Each laboratory shall:

(A) have managerial staff with the authority and resources needed to discharge their duties;
(B) have procedures in place to ensure that its personnel are free from any commercial; financial and other undue pressures which adversely affect the quality of their work;
(C) be organized in such a way that confidence in its independence of judgment and integrity is maintained at all times;
(D) specify and document the responsibility, authority, and interrelationship of all personnel who manage, perform or verify work affecting the quality of calibrations and tests. Such documentation shall include:

(i) job descriptions; and
a description of the lines of responsibility in the laboratory so that proportioned and adequate supervision in ensured.

(2) Laboratory Technical Director. Each laboratory shall appoint a laboratory technical director. The laboratory technical director is responsible for the technical and scientific oversight of all laboratory activities. The laboratory technical director shall certify that personnel with appropriate education and technical background perform all tests for which the laboratory is accredited. The laboratory technical director shall be a full-time member of the staff who supervises the day to day laboratory operations. Each laboratory shall be accredited only after presentation of documentation to the department regarding education and work experience.

(A) Qualifications for laboratory technical director of a chemistry laboratory shall be as follows:

(i) A bachelors degree in chemistry, environmental science, biological sciences, physical sciences or engineering, with a minimum of 24 college semester credit hours in chemistry and at least two years of experience in environmental analysis. A masters or doctoral degree in one of the above sciences may be substituted for one year of experience.
(ii) For laboratories engaged in inorganic analysis only, excluding metals analysis, the laboratory technical director may be a person with an associate's degree in chemistry or environmental science or equivalent with a minimum of 16 college semester credit hours in chemistry and two years of experience performing inorganic environmental analysis.

(B) Qualifications for laboratory technical director of a microbiology and whole effluent

toxicity laboratory shall be as follows:

(i) A bachelors degree in microbiology, biology, chemistry, or environmental science, with a minimum of 16 college semester credit hours in microbiology and biology, and two years experience in environmental analysis. A masters or doctoral degree in one of the above sciences may be substituted for one year of experience.

(ii) For laboratories engaged in microbiological analysis limited to coliform and heterotrophic plate count testing, the laboratory technical director may be a person with an associate degree in science or the equivalent with at least four semester credit hours in microbiology and one year of experience in environmental analysis.

(C) Qualifications for laboratory technical director of a radiochemistry laboratory shall be as follows:

(i) A bachelor degree in chemistry or physics with two years of experience, one year in the supervision of environmental radiochemistry; or

(ii) a masters or doctoral degree in one of the above sciences can be substituted for one year of experience.

(D) A valid treatment plant operator's certificate can be substituted for the above qualifications for a laboratory technical director of a drinking water or wastewater treatment facility engaged in the analysis of environmental samples collected within the state.

(E) One year of supervised experience in environmental analysis can be substituted for the above qualifications for laboratory technical director of an industrial waste facility when the laboratory only analyzes samples collected within the state.

(F) When the laboratory engages in more than one analytical category (chemistry, microbiology, whole effluent toxicity, and radiochemistry), one or more persons may compliment the laboratory technical director provided that each meets the applicable qualifications for the analytical category as specified in paragraph (2) of this section.

(G) Persons working in the capacity of laboratory technical director on the effective date of K.A.R. 28-15-36 may continue to qualify as the laboratory technical director subject to the following conditions:

(i) The person shall be a technical director of the laboratory on the date the laboratory applies for accreditation and shall have been a technical director for the previous 12 months.

(ii) The person will only be approved for those parameters/parametric groups for which he has been the technical director of the laboratory for the previous 12 months.
(iii) A person who is recognized as a technical director under the above conditions, and leaves the laboratory, may be recognized as technical director for the same parameters/parametric groups in another laboratory.

(H) An individual shall not be laboratory technical director of more than one accredited laboratory without authorization from the department. Circumstances to be considered for authorization shall include, but will not be limited to:
(i) Operating hours of the laboratories;
(ii) adequacy of supervision; and
(iii) availability of environmental services in the area.

(3) Quality Assurance Officer (QAO). Each laboratory shall appoint a QAO. The QAO is the person responsible for the laboratory's quality assurance program and it's implementation.

(A) The QAO shall review laboratory quality control data, conduct annual internal laboratory audits, and notify management of deficiencies found in the laboratory's quality system. The QAO shall be free from internal and external influences when evaluating data and conducting audits. The QAO shall have documented training and/or experience in quality assurance/quality control procedures and shall have knowledge of the approved analytical methods and quality system requirements. The QAO shall maintain the laboratory's quality assurance documents up to date.

(B) The QAO duties and responsibilities can also be carried out by the laboratory technical director when staffing is limited.

(C) The QAO shall have direct access to laboratory management.

(D) The QAO shall (when possible) have functions independent from laboratory operations for which they have quality assurance oversight.

(4) Responsibilities of laboratory management. The laboratory management shall have the authority and resources needed to discharge the following duties:

(A) The laboratory management shall be responsible for supervising all personnel

employed by the laboratory, all analytical and operational activities, and for documenting the quality of all data reported.

(B) Laboratory management shall define the minimum level of qualifications, experience, and basic laboratory skills necessary for all positions in the laboratory.

(C) The laboratory management shall ensure all technical laboratory staff have demonstrated capability in the activities for which they are responsible. (See Appendix A)

(D) The laboratory management shall ensure that the training of the laboratory personnel is kept up to date (on-going) by the following.

(i) Documentation that the employee has read, understands and uses the latest version of the laboratory's quality documents;
(ii) training documentation on equipment, technics, or procedures;
(iii) training in ethical and legal responsibilities;
(iv) documentation of analyst(s) continued performance at least once per year by one of the following:

- Acceptable performance of a blind sample;
- another demonstration of capability; (See Appendix A)
- successful analysis of a blind performance sample on a similar method using the same technology;
- analysis of at least four consecutive laboratory control samples with acceptable levels of precision and accuracy; or
- if one of the above can not be performed, the analysis of environmental samples that have been analyzed by another trained analyst with statistically indistinguishable results.

(E) The laboratory management shall ensure all sample acceptance criteria are verified and samples are logged into the sample tracking system and properly labeled and stored.

(F) The laboratory management shall nominate a deputy when the laboratory technical director is absent from the laboratory for more than 15 consecutive calendar days. The appointed deputy shall meet the qualifications for laboratory technical director. The laboratory management shall notify the department in writing when the absence of the laboratory technical director exceeds 65 days.

(G) The laboratory management shall develop a proactive program for prevention and detection of improper, unethical, or illegal actions.

Part III - Laboratory facilities. Accommodation and Environment.

Each laboratory conducting chemical, microbiological, radiochemical or biological analyses shall meet the following requirements:

(1) The laboratory's accommodations, test areas, energy sources, lighting, heating and ventilation shall be as needed for the proper performance of tests.

(2) The facilities in which the analysis is performed shall not have an adverse impact on the test results.

(3) The laboratory shall document the facility's environmental conditions as required by the approved method. Where safety practices are included in an approved method, they shall be strictly followed.

(4) There shall be separation between neighboring areas when the activities therein are incompatible. Access to and use of all areas affecting the quality of data shall be defined and controlled.

(5) Measures shall be taken to ensure good housekeeping and to ensure contamination does not affect data quality.

(6) Sufficient work space shall be available to ensure unencumbered work area. Work areas include access and entryways to the laboratory, sample receipt area, sample storage area, chemical and waste storage area, and data handling and data storage area.

(7) Additional Requirement for Laboratory Facilities for Microbiological Testing. Floors and work surfaces shall be non-absorbent and easy to clean and disinfect. Work surfaces shall be adequately sealed. Laboratories shall provide sufficient storage space. The area shall be clean and free from dust accumulation. Plants, food, and drink shall be prohibited from the laboratory work area.

(8) Additional Requirement for Laboratory Facilities for Toxicity Testing. Laboratory space must be adequate for the types and numbers of tests performed. The building must provide adequate cooling, heating and illumination for conducting testing and culturing; hot and cold running water must be available for cleaning equipment. (Also Part IV.6.B)

Part IV - Laboratory equipment, reference materials, reagents, supplies, and reference standards

(1) Laboratory equipment and reference materials.

(A) All equipment, and reference materials necessary for laboratory analyses shall be on-site for the specific analysis for which the laboratory is to be accredited. In cases where the laboratory needs to use equipment outside its permanent control it shall ensure that all relevant requirements of this standard are met.

(B) All equipment shall be properly maintained, inspected and cleaned. Procedures for maintenance of equipment shall be documented. Maintenance and repairs shall be documented.

(C) Defective equipment or parts shall be removed from service and labeled until repaired. The effect of the defective equipment on previous calibrations or tests shall be examined by the laboratory. Equipment or parts shall not be put back in service until the laboratory demonstrates that its functioning co tly.

(D) When appropriate, equipment and reference material shall be labeled, marked or identified to indicate calibration status.

(E) Records shall be maintained for each equipment and reference materials significant to the test performed. These records shall include documentation on all routine and no-routine maintenance activities and reference material verifications (See Part X.7)

(2) Measurement Traceability and Calibration.

(A) General Requirements. All measuring operations and testing equipment having an effect on the accuracy or validity of tes all be calibrated and/or verified before being put into service and on a continuing basis. The laboratory shall have an established program for the calibration and verification of its measuring and test equipment. This includes balances, thermometers and control standards.

(B) Traceability of Calibration.

(i) The overall program of calib n and/or verification and validation of equipment shall be designed and operated so as to ensure that measurements made by the laboratory are traceable to national standards of measurement.

(ii) Calibration certificates shall indicate the traceability to national standards of

measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification. The laboratory shall maintain records of all such certifications.
(iii) Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons, proficiency testing, or independent analysis.

(C) Quality of Standards and Reagents.

(i) The source of standards shall comply with Part IV.2.B.
(ii) Reagents - In methods where the purity of reagents is not specified, analytical reagent grade shall be used. Reagents of lesser purity than those specified by the test method shall not be used. The labels on the container should be checked to verify that the purity of the reagents meets the requirements of the particular test method. Such information shall be documented.
(iii) Water - The quality of water sources shall be monitored and documented and shall meet method specified requirements.
(iv) The laboratory will verify the concentration of titrants in accordance with written laboratory procedures.
(v) The laboratory shall ensure that the quality of the reagents and media used is appropriate for the test concerned.
(vi) Culture media may be prepared from commercial dehydrated powders or may be purchased ready-to-use. Preparation from different chemical ingredients shall not be done unless the media is not available commercially or unless specified by the method.
(vii) Reagents, commercial dehydrated powders and media shall be used within the shelf-life of the product and shall be documented according to Part X.8.
(viii) Microbiological Testing - Distilled water, deionized water or reverse-osmosis produced water free from bactericidal and inhibitory substances shall be used in the preparation of media, solutions and buffers. The quality of the water shall be monitored for chlorine residual, specific conductance, and heterotrophic bacteria plate count monthly (when in use), when maintenance is performed on the water treatment system, or at startup after a period of disuse longer than one month. Analysis for metals and the Bacteriological Water Quality Test (to determine presence of toxic agents or growth promoting substances) shall be performed annually. Results of these analyses shall meet the specifications of the required method and records of analyses shall be maintained for five years. (An exception to performing the Bacteriological Water Quality Test shall be given to

laboratories that can supply documentation to show that their water source meets the criteria, as specified by the method, for Type I or Type II reagent water.)

Test	**Monitoring Frequency**	**Limit**
Chemical test:		
Conductivity	Monthly	>0.5 megohms/cm resistance or < 2 umhos/cm at 25 EC
pH	With each use	5.5 - 7.5
Heavy Metals, single (Cd, Cr, Cu, Ni, Pb, and Zn)	Annually	< 0.05 mg/L
Heavy metals, total	Annually	#0.1 mg/L
Total residual chlorine	Monthly	<0.1 mg/L
Bacteriological Testing:		
Heterotrophic plate count	Monthly	< 1000 CFU/mL
Water quality test (see Standard Methods, 18th Ed, 9020, and 1080)	Annually	0.8 - 3.0 ratio

(ix) Media, solutions and reagents shall be prepared, used and stored according to a documented procedure following the manufacturer's instructions or the test method. Documentation for media prepared in the laboratory shall include date of preparation, preparer's initials, type and amount of media prepared, manufacturer and lot number, final pH of the media, and expiration date. Documentation for media purchased pre-prepared, ready-to-use shall include manufacturer, lot number, type and amount of media received, date of receipt, expiration date of the media, and pH of the media.
(x) The quality control program shall establish and maintain provisions for radionuclide standards.

- Reference standards that are used in a radiochemical laboratory shall be obtained from the National Institute of Standards and Technology (NIST), EPA, or suppliers who participate in supplying NIST standards or NIST traceable radionuclides. Any reference standards purchased outside the United States shall be traceable back to each country's national standards laboratory.

Commercial suppliers of reference standards shall conform to ANSI N42.22 - 1995 to assure the quality of their products.

- Reference standards shall be accompanied with a certificate of calibration whose content is as described in ANSI N42.22 - 1995, Section 8, Certificates.
- Laboratories should consult with the supplier if the lab's verification of the activity of the reference traceable standard indicates a noticeable deviation from the certified value. The laboratory shall not use a value other than the decay corrected certified value.

(xi) All reagents used for radionuclide testing shall be analytical reagent g or better.

(xii) The grade of all reagents used in toxicity tests is specified in the test method except the reference standard. All refe e standards shall be prepared from chemicals which are analytical reagent grade or better. The preparation of all standards and reference toxicants shall be documented.

(xiii) Only reagent-grade water collected from distillation or deionization units (> 17 megohm resistivity) shall be used to prepare reagents for toxicity testing.

(D) Reference standards.

(i) Ref ce standard of measurement (such as class S weights or equivalent, or thermometers) shall be used for calibrations only.

(ii) Reference standard of measurement shall be calibrated by a body that can provide, where possible, traceability to international or national standard of measurement. When a calibration certificate is availabl shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification. The laboratory shall keep these certificates as part of their records.

(iii) The laborato all have a program in place for the calibration and verification of reference standards.

(iv) Where relevant, reference standards and meas g and testing equipment shall be subjected to in-service checks between calibrations and verifications. Reference materials shall be traceable. Where possible, traceability shall be to national or international standards of measurement, or to national or international standard reference materials.

(3) Calibration of Laboratory Support Equipment. Laboratory support equipm are devices necessary to support laboratory operations but may not be the actual test instrument. These include but are not limited to: balances, ovens, ref rators, freezers, incubators, water baths,

temperature measuring devices (including thermometers and thermistors), thermal/pressure sample preparation devices and volumetric dispensing devices (such as Eppendorf®, or automatic dilutor/dispensing devices) if quantitative results are dependent on their accuracy, as in standard preparation and dispensing or dilution into a specified volume.

(A) Laboratory support equipment shall be maintained in working order. The records of all repairs and maintenance activities including service calls, shall be kept;

(B) All support equipment shall be calibrated or verified at least annually, using NIST traceable references when available, over the entire range of use. The results of such calibration shall be within the specifications required of the application for which this equipment is used or:

(i) The equipment shall be removed from service until repaired; or
(ii) The laboratory shall maintain records of established correction factors to correct all measurements.

(C) records shall be maintained to document instrument performance;

(D) prior to use on each working day, balances, ovens, refrigerators, freezers, incubators, and water baths shall be checked with reference materials in the expected use range. The acceptability for use of these support equipment shall be based on the needs for the application or test. Checks shall be documented.

(E) For chemical test mechanical volumetric dispensing devices including burets (except Class A glassware) shall be checked for accuracy on at least a quarterly use basis. Glass microliter syringes are to be considered in the same manner as Class A glassware, but shall come with a certificate attesting to established accuracy or the accuracy shall be initially demonstrated and documented by the laboratory.

(F) Volumetric Equipment for Microbiology. Volumetric equipment shall be calibrated as follows:

(i) equipment with movable parts such as automatic dispensers, dispensers/diluters, and mechanical hand pipettes shall be calibrated quarterly.
(ii) equipment such as filter funnels, bottles, non-class A glassware, and other marked containers shall be calibrated once per lot prior to first use.
(iii) the volume of the disposable volumetric equipment such as sample bottles, disposable pipettes, and micropippette tips shall be checked once per lot.

(G) For chemical tests the temperature, cycle time, and pressure of each run of autoclaves

shall be documented by the use of appropriate chemical indicators or temperature recorders and pressure gauges.

(H) For microbiological tests that employ autoclave sterilization:

(i) The performance of each autoclave shall be initially evaluated by establishing its functional properties and performance, for example heat distribution characteristics with respect to typical uses. Autoclaves shall meet specified temperature tolerances. Pressure cookers shall not be used for sterilization of growth media.

(ii) Demonstration of sterilization temperature shall be provided by use of continuous temperature recording device or by use of a maximum registering thermometer with every cycle. Appropriate biological indicators shall be used once per month to determine effective sterilization. Temperature sensitive tape shall be used with the contents of each autoclave run to indicate that the autoclave contents have been processed.

(iii) Records of autoclave operations shall be maintained for every cycle. Records shall include: date, contents, maximum temperature reached, pressure, time in sterilization m total run time (may be recorded as time in and time out) and analyst's initials.

(iv) Autoclave maintenance, either internally or by service contract, shall be performed annually and shall include a pressure check and calibration of temperature device. Records of the maintenance shall be maintained in equipment logs.

(v) The autoclave mechanical ng device shall be checked quarterly against a stopwatch and the actual time elapsed documented.

(I) Temperature measuring devices such as liquid-in-glass thermometers, thermocouples, and platinum resistance mometers used in incubators, autoclaves and other equipment shall be the appropriate quality to meet specification(s) in the test method. The graduation of the temperature measuring devices shall be appropriate for the required accuracy of measurement and they shall be calibrated to national or international standards fo mperature (See Part IV.2.B). Calibration shall be done at least annually.

(J) UV instruments, used for sanitization, shall be tested qu rly for effectiveness with an appropriate UV light meter or by plate count agar spread plates. Replace bulbs if output is less than 70% of original for light tests or if count reduction is less than 99% for a plate containing 200 to 300 organisms.

(K) Conductivity meters, oxygen meters, pH meters, hygrometers, and other similar

measurement instruments shall be calibrated before use according to the method specified requirements.

(L) Incubators, Water Baths, Ovens.

(i) The stability and uniformity of temperature distribution and time required after test sample addition to re-establish equilibrium conditions in incubators and water baths shall be established. Temperature of incubators and water baths used for microbiology shall be documented twice daily, at least four hours apart, on each day of use.

(ii) Ovens used for sterilization shall be checked for sterilization effectiveness monthly with appropriate biological indicators. Records shall be maintained for each cycle that include date, cycle time, temperature, contents and analyst's initials.

(4) Outside Support Services and Supplies

(A) Where the laboratory procures outside services and supplies, other than those referred to in this standard, in support of tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's tests.

(B) Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. The laboratory shall, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned.

(C) The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for tests.

(5) Constant and Consistent Test Conditions for Chemical, Radiochemical and Microbiological Testing.

(A) The laboratory shall assure that the test instruments consistently operate within the specifications required of the application for which the equipment is used.

(B) Glassware Cleaning - Glassware shall be cleaned to meet the sensitivity of the test method. Any cleaning and storage procedures that are not specified by the test method shall be documented in laboratory records and SOPs.

(C) Labware (Glassware and Plasticware) for Microbiological testing.

(i) The laboratory shall have a documented procedure for washing labware, if applicable. Detergents designed for laboratory use shall be used.

(ii) Glassware shall be made of borosilicate or other non-corrosive material, free of chips and cracks, and shall have readable measurement marks.

(iii) Labware that is washed and reused shall be tested for possible presence of residues which may inhibit or promote growth of microorganisms by performing the Inhibitory Residue Test annually, and each time the lab changes the lot of detergent or washing procedures.

(iv) Washed labware shall be tested at least once daily, each day of washing, for possible acid or alkaline residue by testing at least one piece of labware with a suitable pH indicator such as bromothymol blue. Records of tests shall be maintained.

(D) To prevent incorrect analysis results caused by the spread of contamination among samples for radiochemical testing, the laboratory shall establish and adhere to written procedures to minimize the possibility of cross contamination between samples.

(E) For gamma spectrometry systems, background check measurements shall be performed each day of use.

(F) For alpha spectrometry systems, background check measurements shall be performed weekly except when using the electro-plating method of sample preparation.

(G) For gas-proportional counter systems, background check measurements shall be performed each day of use.

(6) Constant and Consistent Test Conditions for Toxicity Testing.

(A) If closed refrigerator-sized incubators are used, culturing and testing of organisms shall be separated to avoid loss of cultures due to cross-contamination.

(B) Laboratory space must be adequate for the types and numbers of tests performed. The building must provide adequate cooling, heating and illumination for conducting testing and culturing; hot and cold running water must be available for cleaning equipment.

(C) Air used for aeration of test solutions, dilution waters and cultures must be free of oil and fumes.

(D) The laboratory or a contracted outside expert shall positively identify test organisms to species on an annual basis. The taxonomic reference (citation and page(s))and the names(s) of the taxonomic expert(s) must be kept on file at the laboratory. When organisms are obtained from an outside source the supplier must provide this same information.
(E) Instruments used for routine measurements of chemical and physical parameters such as pH, DO, conductivity, salinity, alkalinity, hardness, chlorine, and weight shall be calibrated, and/or standardized per manufacturer's instructions and Part IV.3. Temperature devices shall be calibrated per Part IV.3. All measurements and calibrations shall be documented.

(F) Test temperature shall be maintained as specified for the test method. Temperature control equipment must be adequate to maintain the required test temperature(s). The average daily temperature of the test solutions must be maintained within 1 ° C of the selected test temperature, for the duration of the test. The minimum frequency of measurement shall be once per 24 hour period. The test temperature for continuous-flow toxicity tests shall be recorded and monitored continuously.

(G) Reagent grade water prepared by any combination of distillation, reverse osmosis, ion exchange, activated carbon and particle filtration, shall meet the following requirements as verified by monthly measurement: conductivity less than or equal to 0.1 umhos or resistivity greater than or equal to 17 megohm, pH 5.5 to 7.5 S.U. and total residual chlorine nondetectable.

(H) The quality of the standard dilution water used for testing or culturing must be sufficient to allow satisfactory survival, growth and reproduction of the test species as demonstrated by routine reference toxicant tests and negative control performance. Water used for culturing and testing shall be analyzed for toxic metals and organics whenever the minimum acceptability criteria for control survival, growth or reproduction are not met and no other cause, such as contaminated glassware or poor stock, can be identified. It is recognized that the analyte lists of some methods manuals may not include all potential toxicants, are based on estimates of chemical toxicity available at the time of publication and may specify detection limits which are not achievable in all matrices. However, for those analytes not listed, or for which the measured concentration or detection limit is greater than the method specified limit, the laboratory must demonstrate that the analyte at the measured concentration or reported detection limit does not exceed one tenth the expected chronic value for the most sensitive species tested and/or cultured. The expected chronic value is based on professional judgement and the best available

scientific data. The "USEPA Ambient Water Quality Criteria Documents" and the EPA AQUIRE data base provide guidance and data on acceptability and toxicity of individual metals and organic compounds.

(I) For each new batch of laboratory-prepared or lot of commercial food used by the laboratory, the performance of organisms fed with the new food shall be compared with the performance of organisms fed with a food of known quality. If the food is used for culturing, its suitability is determined using a measure that evaluates the effect of food quality on survival and growth or reproduction of each of the relevant test species. Where applicable, foods used only in chronic toxicity tests are evaluated using the reference toxicant regularly employed in the laboratory QA program and compared with results of previous test(s) using a food of known quality. In the case of algae, rotifers or other cultured foods, which are collected as a continuous batch, the quality is assessed as described above, each time new nutrient stocks are prepared, a new starter culture is employed or when a significant change in culture conditions occurs. The laboratory shall have written procedures for the statistical evaluation of food acceptance.

(J) Food used to culture organisms used in bioaccumulation tests must be analyzed for the compounds to be measured in the bioaccumulation tests.

(K) Test chamber size and test solution volume shall be as specified in the test method. All test chambers used in a test must be identical.

(L) Test organisms shall be fed the quantity and type food or nutrients specified in the test method. They shall also be fed at the intervals specified in the test methods.

(M) All organisms in a test must be from the same source. Where available certified seeds are used for soil tests.

(N) All organisms used in tests, or used as broodstock to produce neonate test organisms (for example cladocerans and larval fish), must appear healthy, show no signs of stress or disease and exhibit acceptable survival (90% or greater) during the 24 hour period immediately preceding use in tests.

(O) All materials used for test chambers, culture tanks, tubing, etc. and coming in contact with test samples, solutions, control water, sediment or soil or food must be non-toxic and cleaned as described in test methods. Materials must not reduce or add to sample toxicity. Appropriate materials for use in toxicity testing and culturing are described in the referenced manuals.

(P) Light intensity shall be maintained as specified in the methods manuals. Measurements shall be made and recorded on a yearly basis. Photoperiod shall be maintained as specified in the test methods and shall be documented at least quarterly. For algal and plant tests, the light intensity shall be measured and recorded at the start of each test.

(Q) At a minimum, during aquatic chronic testing DO and pH shall be measured daily in at least one replicate of each concentration. In static-renewal tests DO must be measured at both the beginning and end of each 24-h exposure period and may be measured in old and new solutions prior to organism transfer, or after organism transfer; pH is measured at the end of each exposure period (i.e. in old solutions).

(R) The health and culturing conditions of all organisms used for testing shall be documented by the testing laboratory. Such documentation shall include culture conditions (e.g. salinity, hardness, temperature, pH) and observations of any stress, disease or mortality. When organisms are obtained from an outside source, the laboratory shall obtain written documentation of these water quality parameters and biological observations for each lot of organism received. These observations shall adequately address the 24-hour time period referenced in Part IV.6.N above. The laboratory shall also record each of these observations and water quality parameters upon the arrival of the organisms at the testing laboratory.

(S) Age and the age range of the test organisms must be as specified in the test method. Supporting information, such as hatch dates and times, times of brood releases and metrics (for example, chironomid head capsule width) shall be documented.

(T) The maximum holding time of effluents (elapsed time from sample collection to first use in a test) shall not exceed 36 hours and the last use of the sample in test renewals shall not exceed 72 hours without the permission of the permitting authority.

(U) All samples shall be chilled to 4°C during or immediately after collection and handled according to Part V.4.

(V) Organisms obtained from an outside source must be from the same batch. Chronic tests shall have a minimum of four replicates per treatment.

(W) The control population of Ceriodaphnia in chronic effluent or receiving water tests shall contain no more than 20% males.

(X) Dissolved oxygen and pH in aquatic tests shall be within acceptable range at test initiation and aeration (minimal) is provided to tests if, and only if, acceptable dissolved oxygen concentrations cannot be otherwise maintained or if specified by the test method.

(Y) The test soils or sediments must be within the geochemical tolerance range of the test organism.

(Z) An individual test may be conditionally acceptable if temperature, dissolved oxygen, pH and other specified conditions fall outside specifications, depending on the degree of the departure and the objectives of the tests (see test conditions and test acceptability criteria specified for each test method). The acceptability of the test shall depend on the experience and professional judgment of the technical employee and the permitting authority.

Part V - Sample collection, preservation, holding time, and handling.

Each sample shall be properly collected, handled, preserved, stored and analyzed within the required holding time.

(1) Sample collection, preservation, and holding time.

(A) Sample volume, container, preservation, and holding time shall be in the manner prescribed under 40 CFR 136, Table II, July 1, 2002, "Test Methods for Evaluating Solid Waste" Chapter 2, Table 2-36, Third Edition, November 1986, and "Manual for the Certification of Laboratories Analyzing Drinking Water" EPA 815-B-97-001, Table IV-7, Fourth Edition, March 1997.
(B) When the laboratory is responsible for sample collection, the sample collector shall be trained in sampling procedures. A written sampling protocol with specific sampling instructions shall be available to each sample collector.
(C) A sample collection form shall be completed for each sampling event. This form shall contain sampling location, date and time of collection, collector's name, method of preservation, and special remarks concerning the sample.
(D) Each laboratory shall have available an acceptable procedure to track samples from collection through analysis and disposal.

(2) Tracking/Handling of sample.

(A) The laboratory shall have a documented system for the unique identification of samples received at the laboratory. The system shall include identification for all, sub-samples, extracts, and digestates.
(B) Each sample container shall be labeled with an unique identification code (the container physical characteristic is not an acceptable means of identification)
(C) The identification code shall maintain a unique link to the field sample code when in use by the laboratory or their clients.
(D) The identification code shall be placed on the sample container as a durable label.
(E) The identification code shall be entered into the laboratory records (See Part V.4.B.i) and shall be the link that associates the sample with related laboratory activities such as sample preparation or calibration.
(F) In cases where the sample collector and analyst are the same individual or the laboratory preassigns numbers to sample containers, the laboratory identification code may be the same as the field ID code.

(3) Sample Acceptance Policy. Each laboratory shall have a written sample acceptance policy

that clearly outlines the circumstances under which samples shall be accepted or rejected. Data from any samples which do not meet the following criteria shall be flagged in an unambiguous manner clearly defining the nature and substance of the variation. This sample acceptance policy shall be made available to sample collection personnel and shall include, but is not limited to, the following areas of concern:

(A) Proper, full, and complete documentation, which shall include sample identification, the location, date and time of collection, collector's name, preservation type, sample type and any special remarks concerning the sample; (See Part X.3)
(B)) proper sample labeling to include unique identification and a labeling system for the samples with requirements concerning the durability of the labels (water resistant) and the use of indelible ink; (See Part V.2.D)
(C) use of appropriate sample containers; (See Part V.1.A)
(D) adherence to specified holding times; (See Part V.1.A)
(E) adequate sample volume. Sufficient sample volume shall be available to perform the necessary tests; and (See Part V.1.A)
(F) procedures to be used when samples show signs of damage, contamination or inadequate preservation.

(4) Sample Receipt Protocols.

(A) Upon receipt in the laboratory, the condition of the sample, including any abnormalities or departures from standard condition, shall be checked and recorded.

(i) Temperature of samples requiring thermal preservation shall be checked and recorded; All samples which require thermal preservation shall be considered acceptable if the arrival temperature is either within " 2EC of the required temperature or the method specified range. For samples with a specified temperature of 4EC , samples with a temperature ranging from just above the freezing temperature of water to 6EC shall be acceptable. Samples that are hand delivered to the laboratory immediately after collection may not meet this criteria. In these cases, the samples shall be considered acceptable if there is evidence that the chilling process has begun such as arrival on ice.
(ii) Chemical preservation shall be checked prior to or during sample preparation or analysis using readily available techniques.
(iii) Where there is any doubt as to the item's suitability for testing, where the sample does not conform to the description provided, or where the test required is not fully specified, the laboratory shall attempt to consult the client for further instruction before proceeding. The laboratory shall establish whether the sample has received all necessary preparation, or whether the client requires preparation

to be undertaken or arranged by the laboratory. If the sample does not meet the sample receipt acceptance criteria listed in this standard, the laboratory shall either:

- Retain correspondence and/or records of conversations concerning the final disposition of rejected samples; or
- fully document any decision to proceed with the analysis of samples not meeting acceptance criteria. The condition of these samples shall, at a minimum, be noted on the chain of custody or transmittal form and laboratory receipt documents. The analysis data shall be appropriately "qualified" on the final report.

(B) Upon sample receipt, the laboratory shall utilize a permanent chronological record such as a log book or electronic database to document receipt of all sample containers.

(i) This sample receipt log shall record the following:

- Client/Project Name,
- date and time of laboratory receipt,
- unique laboratory ID code (See Part V.2.A), and,
- signature or initials of the person making the entries.

(ii) During the log-in process, the following information shall be unequivocally linked to the log record or included as a part of the log. If such information is recorded/documented elsewhere, the records shall be part of the laboratory's permanent records, easily retrievable upon request and readily available to individuals who will process the sample. Note: the placement of the laboratory ID number on the sample container is not considered a permanent record.

- The field ID code which identifies the container shall be linked to the laboratory ID code in the sample receipt log.
- The date and time of sample collection shall be linked to the sample container and to the date and time of receipt in the laboratory.
- The requested analyses (including applicable approved test method numbers) shall be linked to the laboratory ID code.
- Any comments resulting from inspection for sample rejection shall be linked to the laboratory ID code.

(C) All documentation, such as memos or transmittal forms, that is transmitted to the laboratory by the sample transmitter shall be retained.

(D) A complete chain of custody record form, if utilized, shall be maintained.

(5) Storage Conditions. The laboratory shall store samples, sub-samples, extracts, and digestates according to the specified conditions in the approved methodology. The laboratory shall have documented procedures and appropriate facilities to avoid deterioration, contamination, or damage to the sample during storage, handling, preparation, and testing; any relevant instructions provided with the item shall be followed Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded.

(A) Samples, sample fractions, extracts, leachates, and other sample preparation products shall be stored according to the conditions specified by preservation protocols:

(i) Samples which require thermal preservation shall be stored under refrigeration which is " 2EC of the specified preservation temperature unless method specific criteria exist. For samples with a specified storage temperature of 4EC, storage at a temperature above the freezing point of water to 6EC shall be acceptable.

(ii) Samples shall be stored away from all standards, reagents, food and other potentially contaminating sources. Samples shall be stored in such a manner to prevent cross contamination.

(B) Where a sample or portion of the sample is to be held secure (for example, reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions of concern.

(6) Sample Disposal. The laboratory shall have standard operating procedures for disposal of samples, sub-samples, extracts, digestates, and preparation products.

(7) Subcontracting Analytical Samples.

(A) The laboratory shall advise the client in writing of its intention to subcontract any portion of the testing to another party.

(B) When the laboratory subcontracts any part of the testing, the work shall be placed with a laboratory accredited by the department for the tests to be performed. The laboratory performing the subcontracted work shall be indicated in the final report and non-accredited work shall be clearly identified.

(C) The laboratory shall retain records demonstrating that the above requirements have been met.

Part VI - Analytical methods.

(1) Each drinking water sample analyzed under the safe drinking water act shall be analyzed in accordance with methods and method detection limits approved by the laboratory accreditation officer as required by the safe drinking water act.

(2) Each environmental water sample analyzed under the clean water act shall be analyzed in accordance with methods approved by the laboratory accreditation officer as required by the clean water act.

(3) Each solid and hazardous waste sample analyzed under the resource conservation and recovery act shall be analyzed in accordance with methods approved by the laboratory accreditation officer as required by the resource conservation and recovery act.

(4) Prior to method approval by the department and implementation of the method by the laboratory for the analysis of samples, the laboratory shall prepare a demonstration of capability in accordance with method specification, or when not available, in accordance with guidelines provided by the department (See Appendix A). Demonstration of capability shall be repeated each time there are changes in personnel, methodology, or significant changes in instrumentation. Demonstration of capability shall be documented with all information necessary to reproduce the results. The documentation shall include a demonstration of capability certification statement provided by the department. (See Certification statement)

(5) For analysis of environmental samples for permit or contract requirements for which the use of an EPA promulgated method is not a requirement, the laboratory shall submit to the department for approval the procedure used. The method shall be fully documented and validated (See Appendix A). When applicable, the laboratory shall make the test method available to the client.

(6) Laboratories using work cells shall perform demonstration of capability or method validation as a group. When a member of a work cell changes, the cell as a group shall demonstrate acceptable performance with the first four quality control batches analyzed by the group. If the batch acceptance fails, a new demonstration of capability or method validation shall be performed by the work cell. When the entire work cell changes, a new demonstration of capability or method validation shall be conducted by the group. The work cell performance shall be documented in each member's training records.

(7) Data Verification. Calculations and data transfers shall be subject to appropriate checks.

(A) Each laboratory shall establish Standard Operating Procedure to ensure that the reported data are free from transcription and calculation errors.
(B) Each laboratory shall establish Standard Operating Procedures to ensure that all quality control measures are reviewed, and evaluated before data are reported.
(C) Each laboratory shall establish Standard Operating Procedures addressing manual calculations including manual integrations.

Part VII - Laboratory quality system

Quality Systems include all quality assurance (QA) policies and quality control (QC) procedures, which shall be delineated in a Quality Manual and followed to ensure and document the quality of the analytical data. Each environmental laboratory shall establish and maintain an effective quality system based on the required elements contained in this standard. The quality system shall be appropriate to the type, range, and volume of the environmental testing activities the laboratory undertakes. The quality system shall be documented in the laboratory's quality assurance manual and/or related quality documents. The quality assurance manual shall define and document the laboratory's policies and objectives, and the laboratory's commitment to accepted laboratory practices and quality of testing services. The quality assurance manual, quality documents and standard operating procedures shall be available to, understood by, and implemented by laboratory personnel. The quality assurance manual shall be maintained current under the responsibility of the QAO.

(1) Quality Assurance Manual and Related Quality Assurance Documents. The following are the minimum areas that shall be included in the quality assurance manual and/or related quality documents:

(A) Title Page. The title page shall include:
(i) Document title;
(ii) laboratory's name and address;
(iii) name signature and telephone number of the individual responsible for the laboratory;
(iv) name and signature of the QAO;
(v) effective date; and
(vi) when applicable, identification of all organizational units covered by the manual.

(B) Table of contents, and applicable lists of references, glossaries, and appendices.

(C) Quality Policy Statement. The statement shall include objectives and commitments of management.

(D) Organization and management structure of the laboratory, its relationship to its parent organization, and relevant organizational charts.

(E) The relationship between management, technical operations, support services and the quality system.

(F) Mechanisms for ensuring the laboratory reviews all new work to ensure it has the appropriate facilities and resources before commencing such work.

(G) Procedures for record retention. (See Part X). This section shall also include a procedure for maintenance of documentation through a document control system which ensures that all documents clearly indicate the time period during which the document was in force.

(H) Job descriptions of key staff positions, and reference to job description of other laboratory staff. (See Part II)

(I) Identification of the laboratory's approved signatories; at a minimum, the title page of the Quality Manual shall have the signed and dated concurrence, (with titles) of all responsible parties including the QAO(s), laboratory technical director(s), and the laboratory manager.

(J) Reference to major equipment and reference standards used as well as the facilities and services used by the laboratory in conducting tests. (See Part IV) and (See Part III).

(K) Reference to procedures for calibration, verification, and maintenance of equipment. (See Part IV).

(L) Procedures for achieving traceability of measurement shall be defined. Note: traceability of measurement is accomplished by (1) measurement traceability and calibrations; 2) documentation of reagents and standards, and 3) record keeping. (See Part IV), and (See Part X).

(M) Procedures for dealing with complaints. The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this standard or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with (Part VII.1.V.i). Records of the complaint and subsequent actions shall be maintained.

(N) Procedures for protecting client confidentiality and proprietary rights, if applicable.

(O) Procedures for establishing personnel are adequately experienced and are receiving

the needed training in their duties. (See Part II)

(P) Procedures for the handling of submitted samples. (See Part V)

(Q) Reference to the test procedures used for calibration and or verification. (See Part VIII)

(R) A list of analytical tests and parameters performed by the laboratory shall be compiled. (See Part VI)

(S) Verification practices used by the laboratory which may include use of reference materials, internal quality control procedures, and proficiency testi tudies. (See Part IV), (See Part IX), and (See Part XII).

(T) P dures for reporting analytical results. (See Part XI)

(U) Corrective Action. Procedures to be followed for feedback and corrective action whenever testing discre ies are detected, or departures from documented policies, procedures, and quality control occur. The laboratory management arrangements for exceptionally permitting departures from procedures, policies, or regulations shall be specified. Sample results shall be reported only if all QC measures are acceptable. If the laboratory reports data ciated with failed QC, the data shall be reported with appropriate qualifier(s). These procedures shall include but are not limited to the following:

(i) identification of the individual(s) responsible for assessing QC;
(ii) identification of individual(s) responsible for initiating and/or recommending corrective actions;
(iii) define how the analyst sh treat a data set if the associated QC measurements are unacceptable;
(iv ecify how out of control situations and subsequent corrective actions are to be documented; and
(v) specify procedures for management and QAO to review corrective action rep .

(V) Procedures for audits and data review.

(i) The laboratory shall have procedures for annual internal audits. The internal audit shall be conducted to verify that the laboratory operations continue to comply with the laboratory's quality system. The internal audit shall be conducted by trained and qualified personnel who are, wherever resources permit,

independent of the activity to be audited. Immediate corrective action shall be taken when audit findings cast doubt on the correctness or validity of the calibrations or test results. Clients shall be notified immediately, in writing, when their work is affected by the findings from an internal audit.
(ii) The laboratory shall have procedures for annual management reviews. A review of the quality system shall be completed by management to evaluate its continuing suitability and effectiveness and make any necessary changes or improvements. The annual review shall take into account the outcome of recent internal audits, on-site assessments by external bodies, the results of proficiency tests, any changes in the volume and type of work undertaken, feedback from clients, corrective actions and other relevant factors.
(iii) All audits and review findings and any corrective actions that arise from them shall be documented. Laboratory management shall ensure that corrective actions are discharged within the agreed time frame.
(iv) Performance audits. The laboratory shall ensure the quality of results by implementing checks to monitor the quality of the laboratory's analytical activities. Such checks may include internal quality control procedures using statistical techniques, participation in proficiency testing, use of certified reference materials or in-house quality control using secondary reference materials, replicate testing using the same or different methods, re-testing of retained samples, correlation of results for different but related analysis of a sample.

(W) Ethics policy statement developed by the laboratory and processes/procedures for educating and training personnel in their ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions.

(2) Methods Documentation. The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of samples and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

(A) Standard Operating Procedures (SOPs). Laboratories shall maintain standard operating procedures that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, handling customer complaints, and all test methods.

(i) These documents, for example, may be equipment manuals provided by the manufacturer, or internally written documents.

(ii) The test methods may be copies of published methods as long as any changes or selected options in the methods are documented and included in the methods manual. (See Part VII.2.B)
(iii) Copies of all SOPs shall be accessible to all personnel.
(iv) The SOPs shall be organized.
(v) Each SOP shall clearly indicate the effective date of the document, the revision number and the signature(s) of the approving authority.

(B) Laboratory Method Manual(s). The laboratory shall have and maintain an in-house methods manual(s) for each accredited analyte or test method. This manual may consist of copies of published or referenced test methods or standard operating procedures that have been written by the laboratory in cases where modifications to the published method have been made by the laboratory or where the referenced method is ambiguous or provides insufficient detail. These changes or clarifications shall be clearly described. Each test method shall include or reference where applicable:

(i) Identification of the test method;
(ii) Applicable matrix or matrices;
(iii) Detection limit;
(iv) Scope of the test method;
(v) Summary of the test method;
(vi) Definitions;
(vii) Interferences;
(viii) Safety;
(ix) Equipment and supplies;
(x) Reagents and standards;
(xi) Sample collection, preservation, shipment and storage;
(xii) Quality control;
(xiii) Calibration and standardization;
(xiv) Procedure;
(xv) Calculations;
(xvi) Method performance;
(xvii) Pollution prevention;
(xviii) Data assessment and acceptable criteria for quality control measures;
(xix) Corrective actions for out-of-control or unacceptable data;
(xx) Waste management;
(xxi) References; and
(xxii) Tables, diagrams, flowcharts and validation data.

(C) Sample Aliquots. Where sampling (as in obtaining sample aliquots from a submitted

sample) is carried out as part of the test method, the laboratory shall use documented procedures and appropriate techniques to obtain representative subsamples.

Part VIII - Calibration

Calibration requirements are divided into two parts: (1) requirements for analytical support equipment (See Part IV.3), and 2) requirements for instrument calibration. In addition, the requirements for instrument calibration are divided into initial instrument calibration and continuing instrument calibration verification. The laboratory shall follow instrument calibration requirements as specified by the mandated method. When the mandated method does not specify the calibration requirements, the laboratory shall establish calibration procedures. The calibration procedures shall include the following minimum requirements:

(1) Initial Instrument Calibrations:

(A) The details of the initial instrument calibration procedures including calculations, integrations, acceptance criteria and associated statistics shall be included or referenced in the test method SOP. When initial instrument calibration procedures are referenced in the test method, then the referenced material shall be retained by the laboratory and be available for review.

(B) Sufficient raw data shall be retained for the reconstruction of the initial instrument calibration. Records shall include the following (where applicable):

(i) Calibration date;
(ii) Test method;
(iii) Instrument;
(iv) Analysis date;
(v) Each analyte name;
(vi) Concentrations;
(vii) Response; and
(viii) Calibration curve or response factor.

(C) Sample results shall be quantitated from the initial instrument calibration and shall not be quantitated from any continuing instrument calibration verification.

(D) All initial instrument calibrations shall be verified with a standard obtained from a second source and traceable to a national standard (when available).

(E) Criteria for the acceptance of an initial instrument calibration shall be established. The criteria used shall be appropriate to the calibration technic employed.

(F) When the laboratory reports sample results not bracketed by initial calibration

standards, the sample shall be qualified in the report as having less certainty. The lowest calibration standard used in the initial calibration shall be above the laboratory's detection limit.

(G) When initial instrument calibration results are outside of the established acceptance criteria, corrective action shall be performed. The laboratory shall not report data associated with the unacceptable initial instrument calibration.

(H) Calibration standards shall include concentrations at or below the regulatory limit unless these concentrations are below the laboratory's demonstrated detection limit.

(I) When the m ated method does not specify the number of calibration standards, the minimum number is two, not including blanks or a zero standard. Where applicable, the laboratory shall have a standard operating procedure for the determination of the number of points needed for initial instrument calibration.

(2) Continuing Instrument Calibration Verification. When an initial instrument calibration is not performed on the day of analysis, the validity of the initial calibration shall be verified prior to sample analyses by a continuing instrument calibration verification with each analytical ba

(A) The continuing instrument calibration procedure, calculations and associated statistics shall be referenced or described in the laboratory's test method standard operating procedure.

(B) A continuing instrument calibration verification shall be repeated at the beginning and end of each analytical batch. The concentrations of the calibration verification shall be varied within the established calibration range. When the laboratory uses internal standards, only one concentration per internal standard shall be necessary.

(C) Sufficient raw data shall be retained for the reconstruction of the continuing instrument calibration verification. Records shall include the following (where applicable):

(i) Calibration date;
(ii) Test method;
(iii) Instrument;
(iv) Analysis date;
(v) Each analyte name;
(vi) Concentrations;
(vii) Response; and

(viii) Calibration curve or response factor.

(D) Criteria for the acceptance of a continuing instrument calibration verification shall be established.

(E) When the continuing instrument calibration verification results obtained are outside established acceptance criteria, corrective actions shall be performed. If routine corrective action procedures fail to produce a second consecutive (immediate) calibration verification within acceptable criteria, then either the laboratory has to demonstrate performance after corrective action with two consecutive successful calibration verifications, or a new initial instrument calibration shall be performed. If the laboratory has not demonstrated acceptable performance, sample analyses shall not occur until a new initial calibration curve is established and verified. However, the laboratory may choose to report data from samples associated with an unacceptable calibration verification as qualified data when the following special conditions occur:

(i) When the acceptable criteria for the continuing calibration verification are exceeded high, and there are associated samples that are non detects, then those no-detects may be reported. Otherwise the samples affected by the unacceptable calibration verification shall be re-analyzed after a new calibration curve has been established, evaluated and accepted.

(ii) When the acceptance for the continuing calibration verification are exceeded low, those samples results may be reported if they exceed a maximum regulatory limit/decision level. Otherwise the samples affected by the unacceptable verification shall be re-analyzed after a new calibration curve has been established, evaluated and accepted.

(3) Radiation Measurement System Calibration. Because of the stability and response nature of modern radiation measurement instrumentation, it is not typically necessary to verify calibration of these systems each day of use. This section addresses those practices that are necessary for proper calibration and those requirements of Part VIII that are not applicable to some types of radiation measurement instrumentation.

(A) Initial Instrument Calibration.

(i) Given that activity detection efficiency is independent of sample activity at all but extreme activity levels, the requirements of Part VIII.1.F, H, and I are not applicable to radiochemical method calibrations except mass attenuation in gas-proportional counting and sample quench in liquid scintillation counting Radiochemistry analytical instruments are subject to calibration when purchased, when the instrument is serviced, when the instrument is moved and when the instrument setting(s) have been changed.

(ii) Instrument calibration shall be performed with reference standards as defined in Part IV.2.C.x. The standards shall have the same general characteristics (i.e., geometry, homogeneity, density, etc.) as the associated samples.
(iii) The frequency of calibration shall be addressed in the laboratory method manual Part VII.2.B. if not addressed in the method. A specific frequency (e.g. monthly) or observations from the associated control or tolerance chart, as the basis for calibration shall be specified.

(B) Continuing Instrument Calibration Verification. Calibration verification checks shall be performed using appropriate check sources and monitored with control charts or tolerance charts to ensure that the instrument is operating properly and that the calibration has not changed. The same check source used in the preparation of the tolerance chart or control chart at the time of calibration shall be used in the calibration verification of the instrument. The check sources must provide adequate counting statistics for a relatively short count time and the source should be sealed or encapsulated to prevent loss of activity and contamination of the instrument and laboratory personnel. For alpha and gamma spectroscopy systems, the instrument calibration verification shall include checks on the counting efficiency and the relationship between channel number and alpha or gamma ray energy.

(i) For gamma spectroscopy systems, the calibration verification checks for efficiency and energy calibration shall be performed on a day of use basis along with performance checks on peak resolution.
(ii) For alpha spectroscopy systems, the calibration verification check for energy calibration shall be performed on a weekly basis and the performance check for counting efficiency shall be performed on at least a monthly basis.
(iii) For gas-proportional and liquid scintillation counters, the calibration verification check for counting efficiency shall be performed on a day of use basis. Verification of instrument calibration does not directly verify secondary calibrations, e.g., the mass efficiency curve or the quench curve.
(iv) For scintillation counters the calibration verification for counting efficiency shall be performed on a day of use basis.

(C) Background Measurement. Background measurements shall be made on a regular basis and monitored using control charts or tolerance charts to ensure that the laboratory maintains its capability to meet required data quality objectives. These values are subtracted from the total measured activity in the determination of the sample activity.

(i) For gamma spectroscopy systems, background measurements shall be performed on at least a monthly basis.
(ii) For alpha spectroscopy systems, background measurements shall be

performed on at least a monthly basis.
(iii) For gas-proportional counters background measurements shall be performed on a weekly basis.
(iv) For scintillation counters, background measurements shall be performed each day of use.

Part IX - Quality Control

(1) Quality Control Procedures.

(A) All laboratories shall have detailed written protocols in place to monitor the following quality controls:

(i) Positive and negative controls to monitor tests such as blanks, spikes, reference toxicants;

(ii) Tests to define the variability and/or repeatability of the laboratory results such as replicates;

(iii) Measures to assure the accuracy of the test method including calibration and/or continuing calibrations, use of certified reference materials, proficiency test samples, or other measures;

(iv) Measures to evaluate test method capability such as detection limits and quantitation limits and range of applicability such as linearity;

(v) Selection of appropriate formulas to reduce raw data to final results such as regression analysis, comparison to internal/external standard calculations, and statistical analyses;

(vi) Selection and use of reagents and standards of appropriate quality;

(vii) Measures to assure the selectivity of the test for its intended purpose; and

(viii) Measures to assure constant and consistent test conditions (both instrumental and environmental) where required by the test method such as temperature, humidity, light, or specific instrument conditions.

(B) All quality control measures shall be assessed and evaluated on an on-going basis, and quality control acceptance criteria shall be used to determine the usability of the data.

(C) The laboratory shall have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist.

(D) The quality control protocols specified by the laboratory's method manual (See Part VII.2.B) shall be followed. The laboratory shall ensure that the essential elements outlined in this standard, or the mandated methods or regulations (whichever are more stringent) are incorporated into their method manuals and/or the quality assurance plan. When it is not apparent which is more stringent the QC in the mandated method or regulations is to be followed.

(2) Chemical testing. The following are the minimum quality control requirements for chemical testing:

(A) Negative Control - Method Performance.

(i) Purpose: The method blank is used to assess the preparation batch for possible contamination during the preparation and processing steps. The method blank shall be processed along with and under the same conditions as the associated samples to include all steps of the analytical procedure. Procedures shall be in place to determine if a method blank is contaminated. Any affected samples associated with a contaminated method blank shall be reprocessed for analysis or the results reported with appropriate data qualifying codes.

(ii) Frequency: The method blank shall be analyzed at a minimum of 1 per preparation batch. In those instances for which no separate preparation method is used (example: volatiles in water) the batch shall be defined as environmental samples that are analyzed together with the same method and personnel, using the same lots of reagents, not to exceed the analysis of 20 environmental samples.

(iii) Composition: The method blank shall consist of a matrix that is similar to the associated samples and is known to be free of the analytes of interest.

(iv) Evaluation Criteria and Corrective Action: While the goal is to have no detectable contaminants, each method blank shall be critically evaluated as to the nature of the interference and the effect on the analysis of each sample within the batch. The source of contamination shall be investigated and measures taken to minimize or eliminate the problem and affected samples reprocessed or data shall be appropriately qualified if:

- The concentration of a targeted analyte in the blank is at or above the reporting limit as established by the test method or by regulation, AND is greater than 1/10 of the amount measured in any sample.
- The blank contamination otherwise affects the sample results as per the test method requirements or the individual project data quality objectives.

(B) Positive Control - Method Performance. Laboratory Control Sample (LCS).

(i) Purpose: The LCS is used to evaluate the performance of the total analytical system, including all preparation and analysis steps. Results of the LCS are compared to established criteria and, if found to be outside of these criteria, indicates that the analytical system is “out of control”. Any affected samples associated with an out of control LCS shall be reprocessed for re-analysis or the results reported with appropriate data qualifying codes.

(ii) Frequency: The LCS shall be analyzed at a minimum of 1 per preparation batch. Exceptions would be for those analytes for which no spiking solutions are available such as total suspended solids, total dissolved solids, total volatile

solids, total solids, pH, color, odor, temperature, dissolved oxygen or turbidity. In those instances for which no separate preparation method is used (example: volatiles in water) the batch shall be defined as environmental samples that are analyzed together with the same method and personnel, using the same lots of reagents, not to exceed the analysis of 20 environmental samples.

(iii) Composition: The LCS is a controlled matrix, known to be free of analytes of interest, spiked with known and verified concentrations of analytes. NOTE: the matrix spike may be used in place of this control as long as the acceptance criteria are as stringent as for the LCS. Alternatively the LCS may consist of a media containing known and verified concentrations of analytes or as Certified Reference Material (CRM). All analyte concentrations shall be within the calibration range of the methods. The following shall be used in choosing components for the spike mixtures: The components to be spiked shall be as specified by the mandated test method or other regulatory requirement or as requested by the client. In the absence of specified spiking components the laboratory shall spike per the following:

- For those components that interfere with an accurate assessment such as spiking simultaneously with technical chlordane, toxaphene and PCBs, the spike should be chosen that represents the chemistries and elution patterns of the components to be reported.
- For those test methods that have extremely long lists of analytes, a representative number may be chosen. The analytes selected should be representative of all analytes reported. The following criteria shall be used for determining the minimum number of analytes to be spiked. However, the laboratory shall insure that all targeted components are included in the spike mixture over a 2 year period.
    - For methods that include 1-10 targets, spike all components;
    - For methods that include 11-20 targets, spike at least 10 or 80%, whichever is greater;
    - For methods with more than 20 targets, spike at least 16 components.

(iv) Evaluation Criteria and Corrective Action: The results of the individual batch LCS are calculated in percent recovery. The laboratory shall document the calculation for percent recovery. The individual LCS is compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory shall determine internal criteria and document

the method used to establish the limits or utilize client specified assessment criteria. A LCS that is determined to be within the criteria effectively establishes that the analytical system is in control and validates system performance for the samples in the associated batch. Samples analyzed along with a LCS determined to be "out of control" should be considered suspect and the samples reprocessed and re-analyzed or the data reported with appropriate data qualifying codes.

(C) Positive Control - Method Performance. Sample Specific Controls. The laboratory shall document procedures for determining the effect of the sample matrix on method performance. These procedures relate to the analyses of matrix specific Quality Control (QC) samples and are designed as data quality indicators for a specific sample using the designated test method. These controls alone are not used to judge laboratory performance. Examples of matrix specific QC include: Matrix Spike (MS); Matrix Spike Duplicate (MSD); sample duplicates; and surrogate spikes. The laboratory shall have procedures in place for tracking, managing, and handling matrix specific QC criteria including spiking appropriate components at appropriate concentrations, calculating recoveries and relative percent difference, evaluating and reporting results based on performance of the QC samples.

(D) Positive Control - Method Performance. Sample Specific Controls. Matrix Spike; Matrix Spike Duplicates:

(i) Purpose: Matrix specific QC samples indicate the effect of the sample matrix on the precision and accuracy of the results generated using the selected method. The information from these controls is sample/matrix specific and would not normally be used to determine the validity of the entire batch.

(ii) Frequency: The frequency of the analysis of matrix specific samples shall be determined as part of a systematic planning process (e.g. Data Quality Objectives) or as specified by the required mandated test method.

(iii) Composition: The components to be spiked shall be as specified by the mandated test method. Any permit specified analytes, as specified by regulation or client requested analytes shall also be included. If there are no specified components, the laboratory shall spike per the following:

- For those components that interfere with an accurate assessment such as spiking simultaneously with technical chlordane, toxaphene and PCBs, the spike should be chosen that represents the chemistries and elution patterns of the components to be

reported.

- For those test methods that have extremely long lists of analytes, a representative number may be chosen using the following criteria for choosing the number of analytes to be spiked. However, the laboratory shall insure that all targeted components are included in the spike mixture over a 2 year period.
  - For methods that include 1-10 targets, spike all components;
  - For methods that include 11-20 targets, spike at least 10 or 80%, whichever is greater;
  - For methods with more than 20 targets, spike at least 16 components.

(iv) Evaluation Criteria and Corrective Action: The results from matrix spike/matrix spike duplicate are primarily designed to assess the precision and accuracy of analytical results in a given matrix and are expressed as percent recovery (%R) and relative percent difference (RPD). The laboratory shall document the calculation for relative percent difference. Results are compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory should determine internal criteria and document the method used to establish the limits. For matrix spike results outside established criteria corrective action shall be documented or the data reported with appropriate data qualifying codes.

(E) Positive Control - Method Performance. Sample Specific Controls. Matrix Duplicates:

(i) Purpose: Matrix duplicates are defined as replicate aliquots of the same sample taken through the entire analytical procedure. The results from this analysis indicate the precision of the results for the specific sample using the selected method. The matrix duplicate provides a usable measure of precision only when target analytes are found in the sample chosen for duplication.

(ii) Frequency: The frequency of the analysis of matrix duplicates may be determined as part of a systematic planning process (e.g. Data Quality Objectives) or as specified by the mandated test method.

(iii) Composition: Matrix duplicates are performed on replicate aliquots of actual samples. The composition is usually not known.

(iv) Evaluation Criteria and Corrective Action: The results from matrix duplicates are primarily designed to assess the precision of analytical results in a given matrix and are expressed as relative percent difference (RPD) or another statistical treatment (e.g., absolute differences). The laboratory shall document the calculation for relative percent difference or other statistical treatments. Results are compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory shall determine internal criteria and document the method used to establish the limits. For matrix duplicates results outside established criteria corrective action shall be documented or the data reported with appropriate data qualifying codes.

(F) Positive Control - Method Performance. Sample Specific Controls. Surrogate Spikes:

(i) Purpose: Surrogates are used most often in organic chromatography test methods and are chosen to reflect the chemistries of the targeted components of the method. Added prior to sample preparation/extraction, they provide a measure of recovery for every sample matrix.

(ii) Frequency: Except where the matrix precludes its use or when not available, surrogate compounds shall be added to all samples, standards, and blanks for all appropriate test methods.

(iii) Composition: Surrogate compounds are chosen to represent the various chemistries of the target analytes in the method. They are often specified by the mandated method and are deliberately chosen for their being unlikely to occur as an environmental contaminant. Often this is accomplished by using deuterated analogs of select compounds.

(iv) Evaluation Criteria and Corrective Action: The results are compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory should determine internal criteria and document the method used to establish the limits. Surrogates outside the acceptance criteria shall be evaluated for the effect indicated for the individual sample results. The appropriate corrective action may be guided by the data quality objectives or other site specific requirements. Results reported from analyses with surrogate recoveries outside the acceptance criteria should include appropriate data qualifiers.

(E) Detection Limits. The laboratory shall utilize a test method that provides a detection

limit that is appropriate and relevant for the intended use of the data. Detection limits shall be determined by the protocol in the mandated test method or applicable regulation, e.g., 40CFR Part 136, Appendix B. If the protocol for determining detection limits is not specified, the selection of the procedure shall reflect instrument limitations and the intended application of the test method.

(i) A detection limit study is not required for any component for which spiking solutions or quality control samples are not available such as temperature.

(ii) The detection limit shall be initially determined for the compounds of interest in each test method in a matrix in which there are not target analytes nor interferences at a concentration that would impact the results or the detection limit shall be determined in the matrix of interest (See definition of matrix).

(iii) Detection limits shall be determined each time there is a change in the test method that affects how the test is performed, or when a change in instrumentation occurs that affects the sensitivity of the analysis.

(iv) All sample processing steps of the analytical method shall be included in the determination of the detection limit.

(v) All procedures used shall be documented. Documentation shall include the matrix type. All supporting data shall be retained.

(vi) The laboratory shall have established procedures to relate detection limits with quantitation limits.

(vii) The test method's quantitation limits shall be established and shall be above the detection limits.

(F) Selectivity.

(i) Absolute retention time and relative retention time aid in the identification of components in chromatographic analyses and to evaluate the effectiveness of a column to separate constituents. The laboratory shall develop and document acceptance criteria for retention time windows.

(ii) A confirmation shall be performed to verify the compound identification when positive results are detected on a sample from a location that has not been previously tested by the laboratory. Such confirmations shall be performed on organic tests such as pesticides, herbicides, or acid extractable or when recommended by the analytical test method except when the analysis involves the use of a mass spectrometer. Confirmation is required unless stipulated in writing by the client. All confirmation shall be documented.

(iii) The laboratory shall document acceptance criteria for mass spectral tuning.

(2) Microbiological testing. This standard apply to laboratories undertaking microbiological analysis of environmental samples. Microbiological testing refers to and includes the detection,

isolation, enumeration, or identification of microorganisms and/or their metabolites, or determination of the presence or absence of growth in materials and media.

(A) Sterility Checks and Blanks, Positive and Negative Controls.

(i) Sterility Checks and Blanks. The laboratory shall demonstrate that the filtration equipment and filters, sample containers, media and reagents have not been contaminated through improper handling or preparation, inadequate sterilization, or environmental exposure.

- A sterility blank shall be analyzed for each lot of pre-prepared, ready-to-use medium (including chromofluorogenic reagent) and for each batch of medium prepared in the laboratory. This shall be done prior to first use of the medium.
- For each filtration series in the filtration technique, the laboratory shall prepare at least one beginning and one ending sterility check. When an interruption of more than 30 minutes occurs, the filtration funnels shall be re-sterilized.
- For pour plate technique, sterility blanks of the medium shall be made by pouring, at a minimum, one uninoculated plate for each lot of pre-prepared, ready-to-use media and for each batch of medium prepared in the laboratory.
- Sterility checks on sample containers shall be performed on at least one container for each lot of purchased, pre-sterilized containers. For containers prepared and sterilized in the laboratory, a sterility check shall be performed on one container per sterilized batch with nonselective growth media.
- A sterility blank shall be performed on each batch of dilution water prepared in the laboratory and on each batch of pre-prepared, ready-to-use dilution water with non-selective growth media.
- At least one filter from each new lot of membrane filters shall be checked for sterility with nonselective growth media.

(ii) Positive Controls. Positive culture controls demonstrate that the medium can support the growth of the target organism(s), and that the medium produces the specified or expected reaction to the target organism(s). Each pre-prepared, ready-to-use lot of medium (including chromofluorogenic reagent) and each batch of medium prepared in the laboratory shall be tested with at least one pure culture of a known positive reaction. This shall be done prior to first use of the medium.

(iii) Negative Controls. Negative culture controls demonstrate that the medium does not support the growth of non-target organisms or does not demonstrate the

typical positive reaction of the target organism(s). Each pre-prepared, ready-to-use lot of selective medium (including chromofluorogenic reagent) and each batch of selective medium prepared in the laboratory shall be analyzed with one or more known negative culture controls, i.e. non-target organisms, as appropriate to the method. This shall be done prior to first use of the medium.

(B) Test Variability/Reproducibility. For test methods that specify colony counts such as membrane filter or plated media, duplicate counts shall be performed monthly on one positive sample, for each month that the test is performed. If the lab has two or more analysts, each analyst shall count typical colonies on the same plate. Counts shall be within 10% difference to be acceptable. In a laboratory with only one microbiology analyst, the same plate shall be counted twice by the analyst, with no more than 5% difference between the counts.

(C) Method Evaluation.

(i) Laboratories are required to demonstrate proficiency with the test method prior to first use. This shall be achieved by comparison to a method already approved for use in the laboratory, or by analyzing a minimum of ten spiked samples whose matrix is representative of those normally submitted to the laboratory, or by analyzing and passing one proficiency test series provided by an approved proficiency sample provider. The laboratory shall maintain this documentation as long as the method is in use and for at least 5 years past the date of last use.

(ii) Laboratories shall participate in the Proficiency Test programs as specified in K.A.R. 28-15-35. The results of these analyses shall be used to evaluate the ability of the laboratory to produce acceptable data.

(D) Test Performance.

(i) All growth and recovery media shall be checked to assure that the target organism(s) respond in an acceptable and predictable manner (See Part IX.2.A.ii)

(ii) To ensure that analysis results are accurate, target organism identity shall be verified as specified in the method, e.g. by use of the completed test, or by use of secondary verification tests such as a catalase test.

(E) Selectivity. In order to ensure identity and traceability, reference cultures used for positive and negative controls shall be obtained from a recognized national collection, organization, or manufacturer recognized by the NELAP Accrediting Authority. Microorganisms may be single use preparations or cultures maintained by documented procedures that demonstrate the continued purity and viability of the organism.

(i) Reference cultures may be revived (if freeze-dried) or transferred from slants

and subcultured once to provide reference stocks. The reference stocks shall be preserved by a technique which maintains the characteristics of the strains. Reference stocks shall be used to prepare working stocks for routine work. If reference stocks have been thawed, they shall not be re-frozen and re-used.
(ii) Working stocks shall not be sequentially cultured more than five times and shall not be subcultured to replace reference stocks.

(3) Radiochemical Testing. This standard apply to laboratories undertaking the examination of environmental samples by radiochemical analysis. These procedures for radiochemical analysis may involve some form of chemical separation followed by detection of the radioactive decay of analyte (or indicative daughters) and tracer isotopes where used. For the purpose of this standard procedures for the determination of radioactive isotopes by mass spectrometry (e.g. ICP-MS or TIMS) or optical (e.g. KPA) techniques are not addressed herein.

(A) Negative Controls.

(i) Method Blank - Shall be performed at a frequency of one per preparation batch. The results of this analysis shall be one of the quality control measures to be used to assess the batch. The method blank result shall be assessed against the specific acceptance criteria (See Part VII.2.B) specified in the laboratory method manual (See Part VII.2.B). When the specified method blank acceptance criteria is not met the specified corrective action and contingencies (See Part VII.2.B) shall be followed and results reported with appropriate data qualifying codes. The occurrence of a failed method blank acceptance criteria and the actions taken shall be noted in the laboratory report (See Part XI.1.I).
(ii) In the case of gamma spectrometry where the sample matrix is simply aliquoted into a calibrated counting geometry the method blank shall be of similar counting geometry that is empty or filled to similar volume with ASTM Type II water to partially simulate gamma attenuation due to a sample matrix.
(iii) There shall be no subtraction of the required method blank (See Part IX.3.A.i) result from the sample results in the associated preparation or analytical batch unless permitted by method or program. This does not preclude the application of any correction factor (e.g. instrument background, analyte presence in tracer, reagent impurities, peak overlap, calibration blank, etc.) to all analyzed samples, both program/project submitted and internal quality control samples. However, these correction factors shall not depend on the required method blank result in the associated analytical batch.
(iv) The method blank sample shall be prepared with similar aliquot size to that of the routine samples for analysis and the method blank result and acceptance criteria (See Part VII.2.B) shall be calculated in a manner that compensates for

sample results based upon differing aliquot size.

(B) Positive Controls.

(i) Laboratory Control Samples - Shall be performed at a frequency of one per preparation batch. The results of this analysis shall be one of the quality control measures to be used to assess the batch. The laboratory control sample result shall be assessed against the specific acceptance criteria (See Part VII.2.B) specified in the laboratory method manual (See Part VII.2.B). When the specified laboratory control sample acceptance criteria is not met the specified corrective action and contingencies (See Part VII.2.B) shall be follow The occurrence of a failed laboratory control sample acceptance criteria and the actions taken shall be noted in the laborato eport (See Part XI.1.I).

(ii) Matrix Spike - Shall be performed at a frequency of one per preparation batch for those methods which do not utilize an internal standard or carrier, for which there is a chemical separation process, and where there is sufficient sample to do so. The exceptions are gross alpha, gross beta and tritium which shall require matrix spikes for aqueous samples. The results of this analysis shall be one of the quality control measures to be used to assess the batch . The matrix spike result shall be assessed against the specific acceptance criteria (See Part VII.2.B) specified in the laboratory method manual (See Part VII.2.B). When the specified matrix spike acceptance criteria is not m e specified corrective action and contingencies (See Part VII.2.B) shall be followed. The occurrence of a failed matrix spike acceptance criteria and the actions taken shall be noted in the laboratory report (See Part XI.1.I). The lack of sufficient sample aliquot size to perform a matrix spike shall be noted in the laboratory report.

(iii) The activity of the laboratory control sample shall: (1) be two to ten times the detection limit or (2) at a level comparable to that of routine samples if the sample activities are expected to exceed 10 times the detection limit.

(iv) The activity of the matrix spike analytes(s) shall be greater than ten times the detection limit.

(v) The laboratory standards used to prepare the laboratory control sample and matrix spike shall be from a source independent of the laboratory standards used for instrument calibration.

(vi) The matrix spike shall be prepared by adding a known ac y of target analyte. Where a radiochemical method, other than gamma spectroscopy, has more than one reportable analyte isotope (e.g. plutonium, Pu 238 and Pu 239, using alpha spectrometry), only one of the analyte isotopes n be included in the laboratory control or matrix spike sample at the indicated activity level. However, whe ore than one analyte isotope is present above the specified

detection limit each shall be assessed against the specified acceptance criteria.
(vii) Where gamma spectrometry is used to identify and quantitate more than one analyte isotope the laboratory control sample and matrix spike shall contain isotopes that represent the low (e.g. americium-241), medium (e.g. cesium-137) and high (e.g. cobalt-60) energy range of the analyzed gamma spectra. As indicated by these examples the isotopes need not exactly bracket the calibrated energy range or the range over which isotopes are identified and quantitated.
(viii) The laboratory control sample shall be prepared with similar aliquot size to that of the routine samples for analyses.

(C) Other Controls.

(i) Tracer - For those methods that utilize a tracer (i.e. internal standard) each sample result shall have an associated tracer recovery calculated and reported. The tracer recovery for each sample result shall be one of the quality control measures to be used to assess the associated sample result acceptance. The tracer recovery shall be assessed against the specific acceptance criteria (See Part VII.2.B) specified in the laboratory method manual (See Part VII.2.B). When the specified tracer recovery acceptance cri is not met the specified corrective action and contingencies (See Part VII.2.B) shall be followed. The occurrence of a failed trac ecovery acceptance criteria and the actions taken shall be noted in the laboratory report (See Part XI.1.I).
(ii) Carrier - For those methods that utilize a carrier, each sample shall have an associated carrier recovery calculated and reported. The carrier recovery for each sample shall be one of the quality control measures to be used to assess the associated sample result acceptance. The carrier recovery shall be assessed against the specific acceptance criteria (See Part VII.2.B) specified in the laboratory method manual (See Part VII.2.B). When the specified carrier recovery acceptance criteria is not met the specified corrective action and contingencies (See Part VII.2.B) shall be followed. The occurrence of a failed carrier recovery acceptance criteria and the actions tak hall be noted in the laboratory report (See Part XI.1.I).

(D) Analytical Variability/Reproducibility.

(i) Replicate - Shall be performed at a frequency of one per preparation batch where there is sufficient sample to do so. The results of this analysis shall be one of the quality control measures to be used to assess batch acceptance. The replicate result shall be assessed against the specific acceptance criteria (See Part VII.2.B) specified in the laboratory method manual (See Part VII.2.B). When the specified replicate acceptance criteria is not met the specified corrective action

and contingencies (See Part VII.2.B) shall be followed. The corrective action shall consider the fact that sample inhomogeneity may be a cause of the failed replicate acceptance criteria. The occurrence of a failed replicate acceptance criteria and the actions taken shall be noted in the laboratory report (See Part XI.1.I).

(ii) For low level samples (less than approximately three times the detection limit) the laboratory may analyze duplicate laboratory control samples or a replicate matrix spike (matrix spike and a matrix spike duplicate) to determine reproducibility within a preparation batch.

(D) Detection Limits. Must be determined prior to sample analysis and must be redetermined each time there is a significant change in the test method or instrument type. The procedures employed must be documented and consistent with mandated method or regulation.

(E) Data Reduction. Each result shall be reported with the associated measurement uncertainty. The procedures for determining the measurement uncertainty must be documented and be consistent with mandated method and regulation.

(4) Toxicity Testing. This standard apply to laboratories measuring the toxicity and/or bioaccumulation of contaminants in general. They are applicable to toxicity or bioaccumulation test methods evaluating effluents (whole effluent toxicity or WET), receiving waters, sediments, elutriates, leachates and soils. In addition to the essential quality control standards described below, some methods may have additional or other requirements based on factors such as the type of matrix evaluated. Additional information can be found in the following methods manuals (or most recent edition): EPA/600/4-91/002, EPA/600/4-91/003, EPA/600/4-90/027F (WET testing), EPA/600/4-90/031 (general aquatic toxicity testing), EPA/600/R-94/025, EPA/600/R-94/024, EPA/503/R-91/001, EPA/823/B-98/004 (sediments and elutriates), EPA/600/3-88/029, EPA/600/3-89/013, ASTM E1598-94 AND ASTM 1676-97 (soils), EPA 821-R-02-012 (Acute), EPA 821-R-02-013 (Chronic Fresh Water), EPA 821-R-02-014 (Chronic Marine and Estuaries).

(A) Positive Controls. Reference Toxicants - Reference toxicant tests indicate the sensitivity of the test organisms being used and demonstrate a laboratory's ability to obtain consistent results with the test method.

(i) The laboratory must demonstrate its ability to obtain consistent results with reference toxicants before it performs toxicity tests with effluents or other environmental samples for regulatory compliance purposes.

- To meet this requirement, the intra-laboratory precision must be

determined by performing five or more acceptable reference toxicant tests for each test method and species with different batches of organisms and appropriate negative controls (water, sediment, or soil).

- An intralaboratory coefficient of variation (%CV) is not established for each test method. However, a testing laboratory shall maintain control charts for the control performance and reference toxicant statistical endpoint (such as NOEC or ECp) and shall evaluate the intralaboratory variability with a specific reference toxicant for each test method.

(ii) Ongoing laboratory performance shall be demonstrated by performing regular reference toxicant tests for each test method and species in accordance with the minimum frequency requirement specified in D.2.1.a.3.

- Intralaboratory precision on an ongoing basis must be determined through the use of reference toxicant tests and plotted in quality control charts. The control charts shall be plotted as point estimate values, such as EC25 for chronic tests and LC50 for acute tests, or as appropriate hypothesis test values, such as the NOEC or NOAEC, over time within a laboratory.
- For endpoints that are point estimates (ICp, ECp) control charts are constructed by plotting the cumulative mean and the control limits which consist of the upper and lower 95% confidence limits (+/- 2 std. dev.); these values are re-calculated with each successive test result. For endpoints from hypothesis tests (NOEC, NOAEC) the values are plotted directly and the control limits consist of one concentration interval above and below the concentration representing central tendency (i.e. the mode).
- After 20 data points are collected for a test method and species, the control chart is maintained using only the last 20 data points, i.e. each successive mean value and control limit is calculated using only the last 20 values.
- Control chart limits are expected to be exceeded occasionally regardless of how well a laboratory performs. Acceptance limits for point estimates (ICp, ECp) which are based on 95% confidence limits should theoretically be exceeded for one in twenty tests. Depending on the dilution factor and test sensitivity, control charts based on hypothesis test values (NOEC, NOAEC) may be expected to be exceeded on a similar frequency. Test results which fall outside of control chart limits at a frequency of 5% or less, or

which fall just outside control chart limits (especially in the case of highly proficient laboratories which may develop relatively narrow acceptance limits over time), are not rejected *de facto.* Such data are evaluated in comparison with control chart characteristics including the width of the acceptance limits and the degree of departure of the value from acceptance limits.

- Laboratories shall develop an acceptance/rejection policy for reference toxicant data which considers test dilution factor, test sensitivity (for hypothesis test values), testing frequency, out-of-control test frequency, relative width of acceptance limits and degree of difference between test results and acceptance limits.
- In the case of reference toxicant data which fails to meet acceptance criteria, the results of environmental toxicity tests conducted during the affected period may be suspect and regarded as provisional. In this case the test procedure is examined for defects and the test repeated if necessary, using a different batch of organisms, as soon as possible or the data is qualified.

(iii) The frequency of reference toxicant testing shall comply with the EPA or state permitting authority requirements. The following minimum frequency shall be met:

- Each batch of test organisms obtained from an outside source, field collection or from laboratory spawning of field-collected species not amenable to routine laboratory culture (for example, sea urchins and bivalve mollusks) must be evaluated with a reference toxicant test of the same type as the environmental toxicity test within the seven days preceding the test or concurrent with the test.
- Test organisms obtained from in-house laboratory cultures must be tested with reference toxicant tests at least once each month for each test method. However, if a given species produced by in-house cultures is used only monthly, or less frequently, a reference toxicant test of the same type must be performed with each environmental toxicity test.
- For test methods and species commonly used in the laboratory, but which are tested on a seasonal basis (e.g. sea urchin fertilization tests), reference toxicant tests must be conducted for each month the method is in use.

(iv) This standard do not currently specify a particular reference toxicant and dilution series however, if the state or permitting authority identifies a reference

toxicant or dilution series for a particular test, the laboratory shall follow the specified requirements. All reference toxicant tests conducted for a given test method and species must use the same reference toxicant, test concentrations, dilution water and data analysis methods. A dilution factor of 0.5x or greater shall be used for both acute and chronic tests.

(v) The reference toxicant tests shall be conducted following the same procedures as the environmental toxicity tests for which the precision is being evaluated. unless otherwise specified in the test method (for example, 10-day sediment tests employ 96-h water-only reference toxicant tests). The test duration, dilution or control water, feeding, organism age, age range and density, test volumes, renewal frequency, water quality measurements, and the number of test concentrations, replicates and organisms per replicate shall be the same as specified for the environmental toxicity test.

(B) Negative Control - Control, Brine Control, Control Sediment, Control Soil or Dilution Water.

(i) The standards for the use, type and frequency of testing of negative controls are specified by the test methods and by permit or regulation and shall be followed. A negative control shall be included with each test.

(ii) Appropriate additional negative controls shall be included when sample adjustments (for example addition of sodium hydroxide for pH adjustment or thiosulfate for dechlorination) or solvent carriers are used in the test.

(iii) Test Acceptability Criteria (TAC) - The test acceptability criteria (for example, the whole effluent chronic *Ceriodaphnia* test, requires 80% or greater survival an average 15 young per female in the controls) as specified in the test method must be achieved for both the reference toxicant and the effluent or environmental sample toxicity test. The criteria shall be calculated and shall meet the method specified requirements for performing toxicity tes

(C) Variability and/or Reproducibility. Intralaboratory precision shall be determined on an ongoing basis through the use of further reference toxicant tests and relat ontrol charts as described in Part IX.4.A above.

(D) Test Sensitivity.

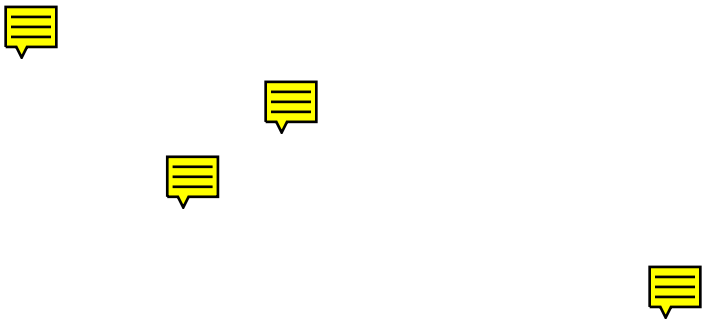
(i) If the Dunnett's procedure is used, the statistical minimum significant difference (SMSD) shall be calculated according to the formula specified by the test method and reported with the test results.

(ii) Estimate the SMSD for non-normal distribution and or heterogenous variances.

(iii) Point estimates: (LCp, ICp, or ECp) - Confidence intervals shall be reported as a measure of the precision around the point estimate value.
(iv) The SMSD shall be calculated and reported for only hypothesis test values, such as the NOEC or NOAEC.

(E) Selection of Appropriate Statistical Analysis Methods.

(i) If required, methods of data analysis and endpoints are specified by language in the regulation, permit or the test method.
(ii) Dose Response Curves - When required, the data shall be plotted in the form of a curve relating the dose of the chemical or concentration of sample to cumulative percentage of test organisms demonstrating a response such as death.



Part X - Records management

The laboratory shall maintain a record to produce unequivocal and accurate documentation of all laboratory activities. The laboratory shall retain all original observations, calculations and derived data, calibration records and copies of the test report. The record keeping system shall facilitate the retrieval of all documentation for inspections and verifications by the laboratory personnel and the accreditation officer. Records shall be kept by the laboratory for not less than five years or as specified by the safe drinking water act, the clean water act, and the resource conservation and recovery act. There are two levels of sample handling: 1) sample tracking and 2) legal chain of custody protocols, which are used for evidentiary or legal purposes. All essential requirements for sample tracking (e.g., chain of custody form) are outlined in Part X.1, Part X.2, and Part X.3. If a client specifies that a sample will be used for evidentiary purposes, then a laboratory shall have a written SOP for how that laboratory will carry out legal chain of custody (e.g., ASTM D 4840-95 and Manual for the Certification of Laboratories Analyzing Drinking Water, March 1997, Appendix A)

(1) Record Keeping System and Design. The record keeping system must allow historical reconstruction of all laboratory activities that produced the analytical data. The history of the sample must be readily understood through the documentation. This shall include interlaboratory transfers of samples and/or extracts.

(A) The records shall include the identity of personnel involved in sampling, sample receipt, preparation, calibration or testing.

(B) All information relating to the laboratory facilities equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, and data verification shall be documented.

(C) The record keeping system shall facilitate the retrieval of all working files and archived records for inspection and verification purposes.,e.g., set format for naming electronic files.

(D) All changes to records shall be signed or initialed by responsible staff. The reason for the signature or initials shall be clearly indicated in the records."

(E) All generated data except those that are generated by automated data collection systems, shall be recorded directly, promptly and legibly in permanent ink.

(F) Entries in records shall not be obliterated by methods such as erasures, overwritten

files or markings. All corrections to record-keeping errors shall be made by one line marked through the error. The individual making the correction shall sign (or initial) and date the correction. These criteria also shall apply to electronically maintained records.

(G) Where computers, automated equipment, or microprocessors, are used for the capture, processing, manipulation, recording, storage or retrieval of test data, the laboratory shall ensure that:

(i) all requirements of this standard are met;
(ii) computer software is tested and documented to be adequate for use;
(iii) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;
(iv) computer and automated equipment are maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data; and,
(v) it establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

(2) Records Management and Storage.

(A) All records (including those pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client. All records shall be available to the laboratory accreditation officer.

(B) All records shall be retained for a minimum of five years from generation of the last entry in the records. All information necessary for the historical reconstruction of data must be maintained by the laboratory. Records which are stored only on electronic media must be supported by the hardware and software necessary for their retrieval.

(C) Records that are stored or generated by computers or personal computers shall have hard copy or write-protected backup copies.

(D) The laboratory shall establish a record management system for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation storage and reporting.

(E) Access to archived information shall be documented with an access log. These records shall be protected against fire, theft, loss, environmental deterioration, vermin

and, in the case of electronic records, electronic or magnetic sources.

(F) The laboratory shall have a plan to ensure that the records are maintained or transferred according to the clients' instructions in the event that a laboratory transfers ownership or goes out of business.

(3) Sample Handling. A record of all procedures to which a sample is subjected while in the possession of the laboratory shall be maintained. These shall include but are not limited to all records pertaining to:

(A) Sample preservation including appropriateness of sample container and compliance with holding time requirement;
(B) Sample identification, receipt, acceptance or rejection and log-in;
(C) Sample storage and tracking including shipping receipts, sample transmittal forms, (chain of custody form); and
(D) The laboratory shall have documented procedures for the receipt and retention of test items, including all provisions necessary to protect the integrity of samples.

(4) Laboratory Support Activities. In addition to documenting all the above-mentioned activities, the following shall be retained:

(A) All original raw data, whether hard copy or electronic, for calibrations, samples and quality control measures, including analysts work sheets and data output records (chromatograms, strip charts and other instrument response readout records);
(B) A written description or reference to the specific test method used which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value;
(C) Copies of final reports;
(D) Archived standard operating procedures;
(E) Correspondence relating to laboratory activities for a specific project;
(F) All corrective action reports, audits and audit responses;
(G) Proficiency test results and raw data; and,
(H) Results of data review, verification, and cross-checking procedures.

(5) Analytical Records. The essential information to be associated with analysis, such as strip charts, tabular printouts, computer data files, analytical notebooks, and run logs, shall include:

(A) Laboratory sample ID code;
(B) Date of analysis and time of analysis is required if the holding time is 72 hours or less

or when time critical steps are included in the analysis, e.g., extractions, and incubations;
(C) Instrumentation identification and instrument operating conditions/parameters (or reference to such data);
(D) Analysis type;
(E) All manual calculations, e.g., manual integrations; and,
(F) Analyst's or operator's initials/signature;
(G) Sample preparation including cleanup, separation protocols, incubation periods, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents;
(H) Sample analysis;
(I) Standard and reagent origin, receipt, preparation, and use;
(J) Calibration criteria, frequency and acceptance criteria;
(K) Data and statistical calculations, review, confirmation, interpretation, assessment and reporting;
(L) Quality control protocols and assessment;
(M) Electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries;
(N) Method performance criteria including expected quality control requirements.

(6) Administrative Records. These records shall include the following:

(A) Personnel qualifications, and experience.
(B) Personnel training (equipment, technic, procedures, ethical, and legal). (See Part II.4.D)
(C) Demonstration of capability for each analyst for each test method. Documentation of work cell performance, when applicable. (See Appendix A) & (See Part VI.4, and).
(D) A log of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory record.

(7) Equipment, reference materials. Documentation shall be maintained for each major item of equipment and all reference materials significant to the tests performed. The records shall include:

(A) the name of the item;
(B) the manufacture's name, type identification and serial number or other unique identification;
(C) date received and date placed in service (if available);
(D) condition when placed in service (new, used, re-conditioned), if available;
(E) current location, when appropriate;
(F) copies of manufacturer's instruction manual when available;

(G) details of maintenance carried out to date and planned for the future; and
(H) dates and results of calibrations and/or verifications;
(I) history of any damage, malfunction, modifications or repairs.

(8) Standards and Reagents. Documented procedures shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory.

(A) The laboratory shall retain records for all standards, reagents and media including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if supplied), the date of receipt, recommended storage conditions, and an expiration date after which the material shall not be used unless its reliability is verified by the laboratory.
(B) Original containers (such as provided by the manufacturer or vendor) shall be labeled with an expiration date.
(C) Records shall be maintained on reagent and standard preparation. These records shall indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date and preparer's initials.
(D) All containers of prepared reagents and standards shall bear a unique identifier and expiration date and be linked to the documentation requirements in Part X.8.C above.

Part XI - Reporting

Test results shall be reported accurately, clearly, unambiguously, and objectively. The results shall be reported in a test report and shall include all the information necessary for the interpretation of the test results and all information required by the method used.

(1) The laboratory shall include the following information when reporting analytical results to an **outside client**:

(A) Report title; name and address of the laboratory, location where the sample was tested if different from the address of the laboratory, contact person and phone number at the laboratory;

(B) unique identification of the report (such as serial number), and unique identification of each page. The total number of pages shall also be part of the report. This requirement may be presented in several ways:

(i) The total number of pages may be listed on the first page of the report as long as the subsequent pages are identified by the unique report identification and consecutive numbers, or

(ii) Each page is identified with the unique report identification, the pages are identified as a number of the total report pages (example: 3 of 10, or 1 of 20).

(iii) Other methods of identifying the pages in the report may be acceptable as long as it is clear to the reader that discrete pages are associated with a specific report, and that the report contains a specified number of pages.

(C) identification of the client and/or project name (when applicable);

(D) identification of the sample included with field sample identification when available;

(E) identification of test results derived from any sample that did not meet the sample acceptance requirements such as improper container, holding time, or temperature;

(F) date of receipt of sample, date and time of sample collection, date(s) of performance of test, and time of sample preparation and/or analysis if the required holding time for either activity is less than or equal to 72 hours;

(G) identification of the test method used, or unambiguous description of any non-standard method used;

(H) if the laboratory collected the sample, reference to sampling procedure;

(I) any deviations from (such as failed quality control), additions to or exclusions from the test method (such as environmental conditions), and any non-standard conditions that may have affected the quality of results, and including the use and definitions of data qualifiers;

(J) measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified; identify whether data are calculated on a dry weight or wet weight basis; identify the reporting units such as µg/l or mg/kg; and for Whole Effluent Toxicity, identify the statistical package used to provide data;

(K) when required, a statement of the estimated uncertainty of the test result;

(L) a signature and title, or an equivalent electronic identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue;

(M) at the laboratory's discretion, a statement to the effect that the results relate only to the items tested or to the sample as received by the laboratory;

(N) at the laboratory's discretion, a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory;

(O) clear identification of all test data provided by outside sources, such as subcontracted laboratories, clients etc; and,

(P) clear identification of numerical results with values outside of quantitation limits.

(2) Laboratories that are operated by a facility and whose sole function is to provide data to the facility management for compliance purposes (**in-house or captive laboratories**) shall have all applicable information specified in Part XI (1) above readily available for review by the laboratory accreditation officer. However formal reports detailing the information are not required if:

A) The in-house laboratory is itself responsible for preparing the regulatory reports; or
B) the laboratory provides information to another individual within the organization for preparation of regulatory reports. The facility management shall ensure that the

appropriate report items are in the report to the regulatory authority if such information is required.

(3) When the report contains results of tests performed by subcontractors, these results shall be clearly identified by subcontractor name or applicable accreditation number.

(4) After issuance of the report, the laboratory report shall remain unchanged. Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Test Report or Test Certificate, serial number . . . [or as otherwise identified]", or equivalent form of wording. Such amendments shall meet all the relevant requirements of this standard.

(5) The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report or test certificate or amendment to a report or certificate.

(6) The laboratory shall, where clients require transmission of test results by telephone, telex, facsimile or other electronic or electromagnetic means, follow documented procedures that ensure that the requirements of this standard are met and that all reasonable steps are taken to preserve confidentiality.

(7) Laboratories accredited to be in compliance with this standard shall certify that the test results
meet all requirements of this standard or provide reasons and/or justification if they do not.

Part XII - Proficiency testing

During participation in a proficiency testing study and before the results of the study are released, the laboratory shall comply with the following conditions:

(1) The laboratory's management and all analysts shall ensure that all PT samples are handled (i.e., managed, analyzed, and reported) in the same manner as real environmental samples utilizing the same staff, methods as used for routine analysis of that analyte, procedures, equipment, facilities, and frequency of analysis.

(2) The laboratory shall not send proficiency testing samples to another laboratory for any analysis for which it seeks accreditation;

(3) The laboratory shall not knowingly accept proficiency testing samples from another laboratory for any analysis for which the sender is seeking accreditation;

(4) The laboratory personnel shall not exchange or offer information about proficiency testing sample results with personnel from another laboratory; and

(5) The laboratory personnel shall not attempt to obtain the true values of any proficiency testing samples from the provider.

Part XIII - Use of accreditation by accredited laboratories.

(1) Each accredited laboratory shall post or display their most recent NELAP accreditation certificate or their NELAP-accredited fields of accreditation in a prominent place in the laboratory facility.

(2) Each accredited laboratory shall make accurate statements concerning the parameters and methods for which they are accredited, and their accreditation status.

(3) Accredited laboratory shall accompany the department's name and/or the NELAP logo with at least the phrase "NELAP accredited" and the laboratory's accreditation number when the names or logo are used on general literature such as catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports or other materials.

(4) Accredited laboratory shall not use their certificate, accreditation status and/or NELAP logo to imply endorsement by the department.

(5) The accredited laboratory choosing to use the department's name, making reference to its accreditation status and/or using the NELAC/NELAP logo in any catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports or other materials, the accredited laboratory shall:

(A) distinguish between proposed testing for which the NELAP-accredited laboratory is accredited and the proposed testing for which the NELAP accredited laboratory is not accredited;
(B) include the NELAP-accredited laboratory's accreditation number.

(6) An accredited laboratory upon suspension, revocation or withdrawal of their accreditation shall:

(A) discontinue use of all catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical results or other materials that contain reference to their past accreditation status and/or display the NELAC/NELAP logo, and,
(B) return all certificates for accreditation to the department.

(7) Incorrect references to the laboratory's accreditation, misleading use of the laboratory's accreditation status and/or unauthorized use of the NELAC/NELAP logo found in catalogs, advertisements, business solicitations, proposals, quotations, laboratory analytical reports or other materials are considered misrepresentation or omission of material facts and therefore

subject to the requirements under K.A.R. 28-15-35(g).

APPENDIX A

DEMONSTRATION OF CAPABILITY

DEMONSTRATION OF CAPABILITY
PROCEDURE FOR DEMONSTRATION OF CAPABILITY

A demonstration of capability (DOC) shall be made prior to using any test method, and at any time there is a significant change in instrument type, personnel or test method (See Part II.4.D.iv, Part VI.4, and Part VI.6). Note: In laboratories with specialized "work cells" (a well defined group of analysts that together perform the method analysis), the group as a unit shall meet the above criteria and this demonstration shall be fully documented.

In general, this demonstration does not test the performance of the me  in real world samples, but in the applicable and available clean matrix (a sample of a matrix in which no target analytes or interferences are present at concentrations that impact the results of a specific test method, i.e.,
water, solids, biological tissue and air) However, before any results are reported using this method, actual sample spike results may be used to meet this standard (i.e.,at least four consecutive matrix spikes within the last twelve months) In addition, for analytes which do not lend themselves to spiking, e.g., TSS, the demonstration of capability may be performed using quality control samples.

All demonstrations shall be documented through the use of the attached form in this appendix. Note: For analytes for which spiking is not an option and for which quality control samples are not readily available, it is the responsibility of the laboratory to document that other approaches to DOC are adequate, this shall be documented under the demonstration of capability in the laboratory's Quality Manual.

The following procedure was adapted from the EPA test methods published in 40 CFR Part 136, Appendix A:

a) A quality control sample shall be obtained from an outside source. If not available, the QC sample may be prepared by the laboratory using stock standards that are prepared independently from those used in instrument calibration.

b) The analyte(s) shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified, or if unspecified, to a concentration approximately 10 times the method-stated or laboratory-calculated method detection limit.

c) At least four aliquots shall be prepared and analyzed according to the test method either concurrently or over a period of days.

d) Using all of the results, calculate the mean recovery (0) in the appropriate reporting units (such as mg/L) and the standard deviations of the population sample (n-1) (in the same units) for each parameter of interest. When it is not possible to determine mean and standard deviations, such as for presence absence and logarithmic values, the laboratory will assess performance against established and documented criteria.

e) Compare the information from (d) above to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or in laboratory-generated acceptance criteria (if there are not established mandatory criteria). If all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the parameters do not meet the acceptance criteria, the performance is unacceptable for that parameter.

f) When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst shall proceed according to 1) or 2) below.

1) Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with c) above.
2) Beginning with c) above, repeat the test for all parameters that failed to meet criteria. Repeated failure, however, will confirm a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all parameters of interest beginning with c).

CERTIFICATION STATEMENT

The following certification statement shall be used to document the completion of each demonstration of capability. A copy of the certification statement shall be retained in the personnel records of each affected employee.

Demonstration of Capability
Certification Statement

Date: Page __of __
Laboratory Name:
Laboratory Address:
Analyst(s) Name(s):
Matrix:
(examples: laboratory pure water, soil, air, solid, biological tissue)
Method number, SOP#, Rev#, and Analyte, or Class of Analytes or Measured Parameters
(examples: barium by 200.7, trace metals by 6010, benzene by 8021, etc.)

The undersigned, CERTIFY that:

1. The analysts identified above, using the cited test method(s), which is in use at this facility for the analyses of samples under the K.A.R. 28-15-35 and the National Environmental Laboratory Accreditation Program, have met the Demonstration of Capability.

2. The test method(s) was performed by the analyst(s) identified on this certification.

3. A copy of the test method(s) and the laboratory-specific SOPs are available for all personnel on-site.

4. The data associated with the demonstration capability are true, accurate, complete and self-explanatory (1).

5. All raw data (including a copy of this certification form) necessary to reconstruct and validate these analyses have been retained at the facility, and that the associated information is well organized and available for review by authorized assessors.

Technical Director's Name and Title	Signature	Date
Quality Assurance Officer's Name and Title	Signature	Date

This certification form shall be completed each time a demonstration of capability study is completed.
(1) True: Consistent with supporting data.
Accurate: Based on good laboratory practices consistent with sound scientific principles/practices.
Complete: Includes the results of all supporting performance testing.
Self-Explanatory: Data properly labeled and stored so that the results are clear and require no additional explanation.